No. 83-196

In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

JOINT APPENDIX

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*The opinion of the district court appears in the appendix to the jurisdictional statement and has not been reproduced.

WILLIAM RUCKELSHAUS, ADMINISTRATOR OF ENVIRONMENTAL PROTECTION AGENCY, DEFENDANT

v.

MONSANTO COMPANY, PLAINTIFF

CAUSE

7 USC 135–136 *et seq,* 5 USC 551 *et seq,* 28 USC 2201 and 2202.. Suit to declare illegal and enjoin implementation of Federal Pesticide Act of 1978, amending Sections 3(c)(1)(D), 3(c)(2)(s) and 10 of 7 USC 135–136 *et seq.* (FIFR Act)

ATTORNEYS

T. Moore, Assistant U.S. Attorney, 1114 Market St., St. Louis, Mo. 63101, 425–4201.

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Gary Dyer, Lathrop Koontz, etc., 2600 Mutual Benefit Life Bldg., 2345 Grand Ave., Kansas City, Mo. 64108, (816) 842–0820.

Kenneth Heineman, Coburn, Croft & Putzell, One Mercantile Ctr., Suite 2900, St. Louis, Mo. 63101, 621–8575.

Co–Counsel: W. Wayne Withers, Monsanto Agricultural Prod. Co., 800 N. Lindbergh Blvd., St. Louis, Mo. 63166, 694–2852.

79–0366C(1) *Monsanto* v. *Costle, et al*

Date	Proceedings
1979	
Mar. 30	Complaint for declaratory judgment, injunctive and other equitable relief; application for preliminary injunction, suggestions in support of application—Fld. Summons Issued (60 Days).
Apr. 10	Marshal's return (summons)—Fld. Served on U.S. Atty. by serving Kathy Hempin 4/2/79.
May 4	Proposed stipulation of facts—Fld. by Pltff. Under seal pursuant to Protective Order of Court. Approved (HKW).

79-0366C(1) *Monsanto* v. *Castle, et al—Continued*

Date	Proceedings
May 4	Motion for protective order; with proposed order; suggestions in support; stipulation; joint motion for entry of pretrial order; with proposed pretrial order, suggestions in support—Fld. by Pltff. Fld. by Both.
May 4	Pretrial order (HKW)—Fld.
May 4	Order (HKW) (protective order)—Fld. Re: Proposed Stipulation of Facts fld. 5/4/79.
May 31	First amended compliant for declaratory judgment, injunctive and other equitable relief—Fld. by Pltff.
June 1	Request to file response to proposed findings of fact and proposed additional findings of fact to be within scope of protective order of May 4, 1979—Memo for clerk fld. by Deft. Leave granted (HKW). Deft's Findings put under seal.
June 4	Request until June 18, 1979 to file response to proposed findings of pretrial order—Memo for Clerk fld. by Pltff. Leave Granted (HKW). CC: Attys.
June 7	Request until May 25, 1979 to file response to proposed findings of fact—Memo for clerk fld. So Ordered (HKW).
June 18	Request to July 2, 1979 to file response to proposed findings of fact of pretrial order—Memo for Clerk fld. by Pltff. Leave Granted (HKW) CC: Atty.
July 2	Response to proposed additional findings of fact—Fld. by Pltff.
July 9	Response to proposed findings of fact—Fld. by Pltff. and Placed under Seal. Entire file placed in Vault.
July 23	Proposed amendment of pre-trial order—fld by pltff.
July 27	Answer—Fld.
Aug. 20	Pretrial conference reset for September 10, 1979—Memo for Clerk fld. by Pltff. Leave Granted (HKW) CC: Atty.
Aug. 30	Proposed additional findings of fact (pages 36-55)—Fld. by Deft.
Aug. 31	Previous date of pretrial conference vacated. Reset on October 29, 1979—Memo for Clerk Fld. by Pltff. Leave Granted (HKW) CC: Attys.
Sept. 5	Request leave to withdraw proposed additional findings fld. 8/30/79 and to replace with correct proposed additional findings of fact—Memo for Clerk fld. by Deft. Leave Granted (HKW).
Oct. 29	W. Wayne Withers enters appearance as co-counsel for pltff—Memo for Clerk fld. by Pltff.
Oct. 29	Pre-trial conference had.
Nov. 1	Stipulation; Stipulation of facts; joint statement of proposed findings of fact as to which the parties do not agree—Fld. by Pltff. and Deft.
Dec. 17	First list of witnesses—Fld. by Pltff.
Dec. 17	Second pre-trial order—Fld. by Pltff. and Deft. So Ordered (HKW).
1980	
Mar. 4	Notice to take deposition—Herbert S. Harrison—4/1/80; Douglas B. Campt—4/2/80; Richard F. Mountford and James L. Skaptason—4/3/80; Thomas E. Adamczyk—4/4/80, fld. by Pltff.
June 20	Notice of Deposition of Dr. Jack Early on 7/2/80 by deft. w/ attached Exhibit A.

79-0366C(1) *Monsanto* v. *Costle, et al—Continued*

Date	Proceedings
July 16	Motion for summary judgment w/Memorandum in Support; and Attachments A thru K, and attached proposed Order, fld. by defts. (Ref. 12/29/81).
July 28	Request for Hearing, fld. by deft.
	8/13/80 Motion of defts. for Summary Judgment fld. on 7/16/80 submitted to Judge Wangelin.
Sept. 2	Deposition of Jack Dent Early taken on behalf of deft. (1 Vol.) fld.
Sept. 8	Memorandum in Opposition to defts. Motion for Summary Judgment, fld. by pltf. Leave to File granted (HKW) (Documents and sealed and not to be opened except by the order of this Court-HKW) placed in Vault.
Sept 17	First Supplemental Stipulation of Facts fld.
Sept. 18	Trial Setting—Order of Court Relating to Trial; Case set for Non-Jury Trial on January 12, 1981, fld. CC: Attys. By Court.
Nov. 13	Motion for a Viewing of Its Premises, fld. by pltff. Monsanto Co. w/Suggestions in Support, fld. (REF. 2/25/81).
Nov. 20	Pre-Trial: List of Witnesses; Designation of Exhibits; fld. by deft.
Nov. 24	Pre-Trial: List of Witnesses; Exhibit List, fld. by pltf.
	12/1/80 Pltffs. Motion for a Viewing of Premises fld. on 11/13/80, Submitted to Judge Wangelin.
Dec. 4	Motion for extension of time to respond to pltf. Motion for Viewing of Premises, w/attached Proposed Order, fld. by deft. (REF 12/4/80).
Dec. 4	Motion for Extension of Time until 12/9/80 to respond to pltfs. Motion fld. 12/4/80, Leave Granted (HKW).
Dec. 10	Stipulation (HKW)—Stipulated and agreed to by and between the parties that Para. 2 of Stipulation entered into on 5/4/79 is hereby amended. Approved (HKW); Second Supplemental Stipulation of Facts, fld.; Third Pre-Trial Order, fld. So Ordered (HKW).
Dec. 15	Memorandum in Opposition to pltffs. Motion for A Viewing of its Premises, fld by deft.
Dec. 24	Reply Suggestions in Support of Motion for a Viewing of Its Premises, Fld by Pltf.
1981	
Jan. 8	Motion for Summary Judgment heard.
Feb. 25	Motion Fld. 11/13/80 by Pltff, Denied at this time (HKW).
Mar. 26	Notice of Termination of Stipulation, by Deft., Fld.
Mar. 26	Motion for Leave to File Supplemental Memorandum, by Deft, fld. w/"Proposed" Suppl. Memorandum in Support of Deft's Motion for Summary Judgment (Ref 3/27/81).
Mar. 27	Motion for Leave to File Suppl. Memo, Granted (HKW) (cc:parties).
Mar. 27	Supplemental Memoranum in Support of Deft's Motion for Summary Judgment, with Attachments, Fld. by Defts.
Apr. 7	Minute entry; Pre-Trial Conference had.
Apr. 7	Pre-Trial Order No. IV; pltff. shall file motion for summary judgment by 5/7/81 and deft. shall respond by 6/23/81; pltff. shall respond to deft's response by 7/7/81. (HKW) cc: all parties.
Apr. 17	Reply to Deft's Suppl. Memo in Support of his Motion for Summary Judgment, by Pltff, fld.

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Date	Proceedings
May 7	Plff's Cross-Motion for Summary Judgment and Attachments, with brief in support, fld. (REF: 12/29/81).
May 8	Deft's Motion for Reconsideration with Memo. in support, fld. (REF: 9-29-81). 5/18/81 Motion of Deft. for Reconsideration, with memo in support fld. 5/8/81, submitted to Judge Wangelin.
May 19	Extension of Time granted to Wednesday, May 27, 1981, within to reply to Deft.'s Motion for Reconsideration of Pre-Trial Order NO. IV. Memo by Pltff. fld. Leave Granted (HKW).
May 27	Response To Deft.'s Motion For Reconsideration, by Pltff fld. 5/27/81—Motion of Deft. For Reconsideration, with memo in support fld. 5/8/81, submitted to Judge Wangelin.
June 19	Motion For Extension of Time, by Deft. fld. So Ordered (HKW) (cc: parties) Until July 10, 1981, to comply with paragraphs 3, 4, and 5 Pretrial Order No. IV and Until July 21, 1981, to comply with paragraph 6 of that order. (Motion fld. with attachments).
July 27	Motion For Leave To File Deft's Response To Pltff's Proposed Findings of Material Facts. Leave to File Granted (HKW).
July 27	Response To Pltff's Proposed Finding of Material Facts, by Deft. fld. (with Attachments).
July 27	Memorandum In Opposition To Monsanto's Cross-Motion For Summary Judgment, by Deft. fld. with attachments).
Aug. 5	Motion For Extension of Time, by Pltff fld. (REF: 8-5-81).
Aug. 5	Order (HKW)—It is hereby ordered that Pltff is grated to and including September 11, 1981, within which to comply with Paragraph 7 of Pre-Trial Order No. IV. (cc: parties).
Aug. 28	Motion For Protective Order, Suggestion In Support Thereof, by Pltff fld.
Aug. 28	Order (HKW)—It Is Hereby Ordered that the deposition of Dr. Dexter B. Sharp shall be maintained in a sealed envelope; It Is Further Ordered that said deposition shall not be disclosed to anyone by Deft. or her counsel and only used by Deft. and her counsel for the purpose of preparation of this action. (cc: parties).
Sept. 11	Reply To Deft's Memorandum In Opposition To Pltff's Cross-Motion For Summary Judgment, by Pltff fld.
Sept. 11	Reply To Deft's Response To Pltff's Proposed Findings of Material Fact and Pltff's Request For Evidentiary Hearing, by Pltff fld. 9/15/81—Cross-Motion for summary judgment fld. by pltff on 5/7/81 w/Responses submitted to Judge Wangelin.
Sept. 29	Order (HKW)—It Is Hereby Ordered that Deft. Anne B. Gorsuch's motion for reconsideration be and is Denied. (cc: parties).
Oct. 5	Letter Re: Three claims contained in Pltff's Reply to Deft's Response to Pltff's Proposed Findings of Fact and Request Evidentiary Hearing, fld. by Deft.
Dec. 4	Pursuant to Honorable H. Kenneth Wangelin's instruction, Cause Set For Non-Jury Trial on Monday, December 28, 1981 at 10:00 a.m. (cc: parties).
Dec. 8	Pursuant to Judge Wangelin's Instructions, Non-Jury Trial Setting of December 28, 1981 Is Vacated. Cause Is Passed To Further Order.

79-0366C(1) *Monsanto* v. *Costle, et al—Continued*

Date	Proceedings
Dec 29.....	Memorandum and Order (HKW)—It Is Hereby Ordered that Pltff's motion for summary judgment be and is Denied; and It Is Further Ordered that Deft's motion for summary judgment be and is Denied. (cc: parties).
1982	
Jan. 13.....	Cause Set for Non-Jury Trial on March 8, 1982.—The Order of Court Relating to Trial is attached herewith. (cc: parties by letter of Court).
Feb. 26.....	Witness List, Exhibit List and Deposition List, by Deft. fld.
Feb. 26.....	Pretrial Compliance and Certificate of Service, by Pltff. fld. (List of Witnesses, Proposed Depositions (and previous trial testimony to be offered in evidence), Exhibit List).
Mar. 3.....	Statement of Objections To Pltff's Exhibits, by Deft. fld.
Mar. 3.....	Objections To Deft's Exhibits, by Pltff. fld.
Mar 8.....	Non-Jury Trial (1st Day)—Parties present for trial. Pltff. evidence commenced but not concluded. Proceedings postponed until tomorrow at 10:00 a.m. Ordered that transcript be suppressed and sealed.
Mar. 8.....	Deposition of Will D. Carpenter, Ph.D., taken on behalf of the Deft., fld.
Mar. 9.....	Deposition of Dexter B. Sharp. Ph.D., taken on behalf of the Deft., fld.
Mar. 9.....	Deposition of Nicholas Lee Reding, taken on behalf of the Deft., fld.
Mar. 9.....	Deposition of Fred Warren Slife, Ph.D., taken on behalf of the Deft., fld.
Mar. 9.....	Non-Jury Trial (2nd Day)—Parties present. Pltff. evidence resumed but not concluded. Proceedings postponed until tomorrow at 10:00.
Mar. 10.....	Non-Jury Trial (3rd Day)—Parties present. Pltff. evidence resumed and concluded. Oral motions of Pltff. & Deft. for directed verdict at close of Pltff's case made, and denied. Pltff. & Deft. granted leave to file written motion. Deft. evidence commenced but not concluded. Proceedings postponed until tomorrow at 10:00.
Mar. 11.....	Non-Jury Trial (4th Day)—Parties present. Deft. evidence resumed but not concluded. Proceedings postponed until tomorow at 10:00 a.m.
Mar. 12.....	Non-Jury Trial (5th Day)—Parties present. Deft. evidence resumed and concluded. Pltff. granted 30 days to file brief; Deft. granted 30 days to respond; Pltff. granted 5 days to reply at which time cause will be taken under submission. Briefing schedule to commence upon receipt of transcript. Record will remain open for 7 days. If Pltff. file earlier time will start at this time.
Mar. 19.....	Designation of Deposition and Prior Trial Testimony To Be Offered by Deft. As Evidence, by Deft. Anne M. Gorsuch fld.
Mar. 31.....	Letter to Mr. Shrybman regarding the return of seven envelopes, together with microfiche that was all received by Monsanto.
Apr. 21.....	Copy of letter that was sent to Judge Wangelin without the heading reference to the Monsanto docket, fld.

Date	Proceedings
May 25	Motion For Order to Show Cause Why Deft., Anne M. Gorsuch, Administrator, Evironmental Protection Agency, Should not Be Held In Contempt of This Court and For An Order Directing Deft. To Deposit Certain Documents With This Court and For Such Other Orders Appropriate Under The Circumstances, Suggestions In Support Thereof, by Pltff. fld. (8-31-82).
May 25	Order (HKW) It Is Hereby Ordered that Deft. Anne M. Gorsuch, appear at a hearing to be held the 14th of June, 1982, in Room 1 of the U.S. Courthouse, St. Louis, MO, and show cause why she should not be held in contempt for violating this Court's Order of April 7, 1981; It Is Further Ordered that Deft., Anne M. Gorsuch, immediately and forthwith obtain from Clausen Ely, Jr. all documents disclosed and transmitted to Mr. Ely regarding glyphosate, along with all copies of said documents which Mr. Ely may have made or directed be made, along with all notes and memoranda which may have been prepared by Mr. Ely or others acting with him relating to such documents, and that deft. obtain from Mr. Ely and all parties to whom the documents or copies were disclosed, a written affirmation that all such copies have been delivered to deft. and that no further use will be made of said documents. It is further ordered that all documents so obtained by deft. shall immediately and forthwith be deposited with this Court pending the hearing on the Order to Show Cause, on the 14th of June, 1982. (cc: parties).
May 25	For Post Trial Discovery, Suggestions In Support Thereof, by Pltff. fld.
May 25	Order (HKW)—It Is Hereby Ordered, on the Motion of Pltff. Monsanto Co., and for good cause shown that pltff. be allowed to conduct post-trial discovery in this cause for the purpose of preparation for the hearing on the 14th day of June, 1982, on the Order to Show Cause. (cc: parties)
May 26	Notice To Take Deposition of Therese Murtagh, by Pltff fld.
May 26	Notice to Take Deposition of Timothy Thomas by Pltff. fld.
May 26	Notice to Take Deposition of Clausen Ely, Jr., by Pltff. fld.
June 7	Motion For An Order Directing Clausen Ely, Jr. To Provide the Identity of All Persons To Whom Disclosure of Pltff's data Has Been Made w/Suggestions In Support Thereof, by Pltff. fld. (REF: 6-7-8).
June 7	Order (HKOW)—It Is Hereby Ordered, Adjudged and Decreed that Mr. Clausen Ely, Jr. shall immediately and forthwith furnish a written affirmation to Pltff. deft. and this Court setting out the identity of any and all persons and the identity of any entity or entities employing such persons or on whose behalf each such person was acting to which the documents, copies thereof, or any information contained therein were disclosed by Mr. Ely or anyone acting on his behalf. (cc: parties).
June 14	Letter regarding response to Order of 6/7/8 fld by Clausen Ely, Jr.
June 25	Deposition of Clausen Ely, Jr. taken on behalf of the Pltff., fld.
June 25	Deposition of Timothy Thomas, taken on behalf of the Pltff. fld.

79-0366C(1) *Monsanto* v. *Costle, et al—Continued*

Date	Proceedings
June 25	Deposition of Therese Murtagh (2 Volumes), taken on behalf of the Pltff. fld.
June 25	Exhibits fld. pertaining to the three (3) depositions fld. on this date.
June 30	Copies of a decision entered on June 22, 1982 by the Third Circuit Court in the consolidate appeals Mobay Chemical Corp. v. Anne M. Gorsuch, Nos. 81-2190/2191 (3rd Cir.), and Pennwalt Corp. v. Anne M. Gorsuch, No. 81-2469 (3rd Cir.) fld.
July 13	Transcript of Trial, fld.
Aug. 12	Post-Trial brief, by Pltff. fld.
Aug. 12	Proposed Conclusions of Law, by Pltff. fld.
Aug. 12	Proposed Findings of Facts, by Pltff. fld.
Aug. 31	Withdrawal of Motion To Show Cause and Motion To Vacate Order To Show Cause, by Pltffd. fld.
Aug 31	Order (HKW)—Upon withdrawal of Motion to Show Cause by Monsanto and for good cause shown, this Court's May 25, 1982 Order that deft. Anne M. Gorsuch show cause why she should not be held in contempt for violating this Court's Order of April 7, 1981 is HEREBY VACATED. (cc: Parties)
Aug. 31	Order (HKW)—This Court Hereby Ordered That: I. Deft. Shall comply with the following procedures prior to any release of documents (including any written, recorded, transcribed, punched, taped, filmed or graphic matter of any kind or description, however produced or reproduced) in the possession of the Agency which although not themselves submitted by Monsanto Co., are determined to contain or discuss data submitted by Monsanto in support of its pesticide registrations. A. Prior to release of any such documents, the Agency shall prepare the documents in the exact form in which disclosure is proposed, including any deletions to the documents. B. A copy of the proposed disclosure shall be provided to Monsanto's company counsel at 800 North Lindbergh Blvd., St. Louis, Mo, by certified mail and a duplicate copy made available to Monsanto's Washington office at the same time. C. If Monsanto informs the Agency of objection to any portion of the disclosure within ten business days of certified return receipt of the proposed disclosure, the Agency shall provide Monsanto's Company counsel by certified mail a copy of the Agency's final proposal for release incorporating its response to the objections raised by Monsanto and shall make a duplicate copy available to Monsanto's Washington office at the same time.

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	D. If Monsanto informs the Agency of contained objections to any portion of the disclosure within five business days of receipt by Monsanto's company counsel of this notice, the Agency shall provide Monsanto's company counsel with a final notice of its intent to release the objectionable document(s) at least thirty days prior to release of the document(s). A duplicate copy shall be made available to Monsanto's Washington office at the same time. II. Nothing in this Order shall be construed to restrict EPA's publication or public release in connection with its official duties of materials which have been expressly prepared to be publicly available for official reasons unrelated to the requirements of Sections 3(c)(2)(A) and 10 of FIFRA or of the Freedom of Information Act. Examples of such materials include preambles to tolerance regulations, technical support documents associated with registration standards or other regulatory actions, and similar documents. III. This relief is granted without prejudice to Monsanto's right to request the same or related relief as part of the final judgment in this case. IV. This Order does not replace or modify any provisions of Pretrial Order IV previously entered in this case. (cc: parties).
Aug. 31.....	Judgment (HKW)—It is Hereby Ordered, Adjudged and Decreed That: I. The Administrator of the Environmental Protection Agency shall establish procedures to accomplish the following: (1) Upon entry of this Judgment and return of the herein described documents by this Court, the Administrator shall maintain in a secured damageproof repository the actual documents obtained by Deft. and submitted to this Court and the additional documents identified by the parties with the parties' joint motion as possible subjects of the disclosure (hereafter "disclosed documents"). (2) The Administrator shall identify all applications for registrations of pesticide products received after May 7, 1982 which contain glyphosate (N-phosphonomethylglycine); or any N-oxide of N-carboxymethyl glyphosate; or any salts, esters, amides, thioacids, thioesters, acid chlorides or combinations thereof, of N-phosphonomethylglycine or of any N-oxide of N-carboxymethyl glyphosate (hereafter "covered application"). (3) For each "covered application, the Administrator shall determine whether supporting data is submitted in any of the following subject areas: Toxicology, Residue and metabolism, Environmental fate in soil.

Date	Proceedings
	(4) For each covered application, the Administrator shall submit the confidential statement(s) of formula and any supporting data in the above identified subject areas to the Scientific Advisory Panel (hereafter "SAP or Panel") established pursuant to 25(d) of FIFRA together with the actual disclosed documents identified in item 1 above. (5) the Administrator shall provide instructions to the Panel that it review the materials submitted to it in order to determine whether the materials submitted with the covered applications have been developed independently of the disclosed information. EPA shall provide to the Panel copies of the unexpurgated originals from which the disclosed documents were prepared. The applicant or Monsanto may make presentations to the Panel and answer any inquiries put by the Panel, but neither may have access to the other's data or formula information without the other's consent. The Panel may also request any additional information from EPA which it deems appropriate. All deliberations of the Panel shall be in executive session. II. If a majority of the SAP determines that the materials in the covered application contain only information that was developed independently of the information contained in the disclosure documents, the Administrator shall certify that the covered application is formally accepted for review by the Agency unless he finds that the SAP did not have substantial information before it to support its finding. If a majority finds that any materials in the covered application were not developed independently of the information contained in the disclosed documents, the Administrator shall deny the application unless he finds that the SAP did not have substantial information before it to support its finding. If no majority of the SAP can make either finding, the SAP shall submit a written report of its conclusions, including those of individual members, to the Administrator who shall, within sixty days of receipt of the SAP report, determine whether to certify formal acceptance of the application for registration or deny the application and shall state the reasons therefor. If the Administrator finds that the SAP did not have substantial information before it to support a finding made by the majority, he shall, within 60 days of receipt of the SAP finding, determine whether to certify formal acceptance of the application or deny the application and shall state the reasons therefor.

Date	Proceedings
	III. The Administrator shall notify the applicant and Monsanto within three business days by certified mail of all certifications and denials under Part II of this Order. Any such certifications shall be final Agency actions not committed to Agency discretion by law and therefore judicially reviewable in the district courts pursuant to 16(a) of FIFRA. Any such denials shall be pursuant to 3(c)(6) of FIFRA and the applicant shall have the remedies set forth in FIFRA relating to Agency refusals to register pesticide products pursuant to 3(c)(6). IV. During any period of time when there is not a validly constituted Scientific Advisory Panel established under 25(d) of FIFRA, the Administrator shall convene an advisory panel of no fewer than three members drawn from the members of the Scientific Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Under those circumstances, the advisory panel shall perform the functions assigned to the Scientific Advisory Panel in Part I and II of this Order. All responsibilities of the Administrator under this Judgment may be performed by a properly designated delegate. V. Judgment requiring the terms and conditions is hereby entered. (cc: parties).
Aug. 31.....	Motion For Order Relating To Disclosures of Agency Documents Containing Monsanto Data submittals w/Memo In Support Thereof, by parties fld. (REF: 8-31-82).
Aug. 31.....	Joint Motion For Judgment Establishing Precedures To Evaluate Registration Applications In Light Of Disclosures of Monsanto Date, w/Memo in support thereof, by parties fld. (REF: 8-31-82).
Sept. 13.....	Post-Trial Brief, Proposed Findings of Fact and Proposed conclusion of Law, by Deft. fld.
Sept. 20.....	Reply Brief, by Pltff. fld. 9/23/82—Briefs having been filed, cause submitted to Judge Wangelin.
Oct. 27.....	Replacement of Page 2 of the Judgment entered by the Court on August 31, 1982, by parties fld. Substitution Ordered (HKW).
Nov. 22.....	Order (HKW)—It Is Hereby Ordered that the Clerk of this Court shall turn over to Kenneth R. Heineman, atty for Pltf., for transfer to an appropriate official of the Environmental Protection Agency, the originals of the documents referred to in the aforementioned Judgment as the "disclosed documents" which were previously transmitted to this Court by Rosanne Mayer of the U.S. Dept. of Justice with her letter to this Court dated June 1, 1982.
Nov. 29.....	Receipt of the originals of the documents, referred to in the Judgment as the "disclosed documents" which have been previously transmitted to the Court by Rosanne Mayer of the U.S. Dept. of Justice with her letter of June 1, 1982. Transfer of these documents to an appropriate official of the Environmental Protection Agency will be made, who will then maintain the Documents in accordance with Paragraph I(1) of the Judgment. (Receipt fld. by Kenneth R. Heineman).

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Date	Proceedings
Dec. 3.....	Letter To Judge Wangelin fld. by Pltf. 1/11/83—Briefs re-submitted to Judge Wangelin.
1983	
Jan. 28.....	Letter Directed To Judge Wangelin from Kenneth Heineman requesting that the attention of the Judge is brought to two recent decisions of the Supreme Court of the U.S. which directly support the positions advanced and authorities relied upon by Monsanto herein, fld.
Feb. 1.....	Letter To Judge Wangelin from Kenneth Heineman calling attention to two recent decisions of the Supreme Court of the U.S.—*U.S.* v. *Security Industrial Bank* and *Northern Pipeline Construction Co.* v. *Marathon Pipeline Co., fld.*
Feb 22.....	Letter To Judge Wangelin in Response to the letter of Kenneth R. Heineman, atty for Monsanto, dated Jan. 28, 1983, fld. by Rosanne Mayer, Atty Environmental Defense Section.
Mar. 9.....	Memorandum In Response To Issues Raised In Conference with Court (in letterform addressed to Judge Wangelin), by Pltff. fld.
Mar. 10.....	Supplemental Post-Trail Brief, by Deft. fld.
Apr. 12.....	Judgment (HKW)—It Is Hereby Ordered, Adjudged and Decreed that §§ 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by Federal Pesticide Act of 1978, 7 U.S.C. § 136 *et seq.*, are unconstitutional and unlawful and that they are beyond any power conferred by Congress by Article I, § 8, Clause 3 of the Constitution of the U.S. and are in violation of the Fifth Amendment thereto; It Is Further Ordered, Adjudged and Decreed that Deft., his officers, agents, employees and representatives be and they are hereby Permanently Enjoined from the implementation and enforcement, in any manner, directly or indirectly, of §§ 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978; and It Is Further Ordered, Adjudged and Decreed that § 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978, does not authorize the deft. to use or consider in support of another's application for registration any of Pltff's information, research and test data submitted prior to January 1, 1970, and such use and consideration thereof by Deft. without Pltff's express written permission is unlawful; and It Is Further Ordered, Adjudged and Decreed that deft., his officers, agents, employees and representatives be and they are hereby Permanently Enjoined from any use or consideration for or disclosure to any other person of any of Pltff's information, research and test data, whenever submitted to deft. or his predecessors unless deft. shall have first obtained pltff's express written permission.

79-0366C(1) *Monsanto* v. *Costle, et al—Continued*

Date	Proceedings
	It Is Further Ordered that a Memorandum Opinion detailing the findings of fact and conclusions of law in support of this Judgment shall issue within six (6) days of this Judgment. (cc: parties).
Apr. 19	Memorandum (HKW), fld. (Pursuant to the Judgment entered on 4/12/83) (cc: parties).
Apr. 22	Motion For Amendment of Judgment For Clarification w/Suggestions In Support and Affidavit of W. Wayne Withers, by Pltff. fld. (REF: 5-9-83).
Apr. 22	Motion To Alter or Amend Judgment and Memorandum In Support Thereof, by Deft. fld. (REF: 5-9-83).
Apr. 22	Motion For Stay Pending Appeal, by Deft. fld. (REF: 5-9-83).
May 2	Response In Opposition To Deft's Motion For Stay Pending Appeal, by Pltff. fld.
May 2	Response In Opposition To Deft's Motion To Alter or Amend Judgment, by Pltff. fld.
May 2	Memorandum In Opposition To Pltff's Motion For Amendment of Judgment For Clarification, by Deft. fld.
May 2	Motion For Leave To File Brief Amicus Curiae To Oppose Deft's Motion For Stay Pending Appeal, by attys for Amici Curiae fld. (REF: 5-2-83).
	5/5/83—Motion For Amendment of Judgment For Clarification fld. by Pltf. on 4/22/83 and Memo In Opposition fld. by Deft. on 5/2/83 submitted to Judge Wangelin.
	5/5/83—Motion To Alter or Amend Judgment and Motion For Stay Pending Appeal fld. by Deft. on 4/22/83 and Responses In Opposition to those motions fld. by Pltff. on 5/2/83 submitted to Judge Wangelin.
May 6	Motion For Order Shortening Time For Briefing and Hearing of Applicants' Application for leave to intervene under Rule 24, w/Memo of Points and Authorities In Support Thereof, by AFL-CIO and Natural Resources Defense Council, Inc. fld. (REF: 6-2-83).
May 6	Declaration of Michael Rubin In Support of Applicants' Motion For Order Shortening Time, fld.
May 6	Notice of Application And Application To Intervene w/Memo In Support Thereof, by AFL-CIO and Natural Resources Defense Council, Inc. fld. (REF: 6-2-83).
May 6	Declaration of Albert H. Meyerhoff, fld. 5/9/83—Morris Levin appeared before the Court relative to a Motion to Intervene. Extension of Time Granted until 6/6/83 per Oral Order of (HKW) to appeal for AFL-CIO. Court delayed ruling of Motion to Intervene. Hearing on said motion may be held.
May 9	Nunc Pro Tunc Order (HKW)—It Is Hereby Ordered that page 39, lines 12 through 13 of the Court's Memorandum Opinion filed April 10, 1983 shall read as follows: contrary, the trial record amply demonstrates that competition in the pesticide industry is healthy and vibrant. (cc: parties).

Date	Proceedings
May 9	Order (HKW)—It Is Hereby Ordered that except as set out in the Court's Amended Judgment of May 9, 1983, all post-trial motions filed by Monsanto Company and the EPA be and are Denied. (cc: parties).
May 9	Amended Judgment (HKW)—It Is Hereby Ordered, Adjudged and Decreed that Sec. 3(c)(1)(D), the last sentence of Sec. 3(c)(2)(a), Sec. 10(b) and Sec. 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act therein after FIFRA, as amended by the Federal Pesticide Act of 1978, 7 U.S.C. Sec. 136 *et seq.*, are unconstitutional and unlawful and that they are beyond any power conferred by Congress by Article I, Sec. 8, Clause 3 of the Constitution of the U.S. and are in violation of the Fifth Amendment thereto; and It Is Further Ordered, Adjudged and Decreed that Deft., his officers, agents employees and representatives be and they are Permanently Enjoined from the implementation and enforcement, in any manner, directly or indirectly, of Sec. 3(c)(1)(D), the last sentence of Sec. 3(c)(2)(A), Sec. 10(b) of FIFRA, as amended by the Federal Pesticide Act of 1978; and It Is Further Ordered, Adjudged and Decreed that Sec. 3(c)(1)(D) of FIFRA, as amended by the Federal Pesticide Act of 1978, does not authorize the Deft. to use or consider in support of another's application for registration any of Pltff's information, research and test data submitted prior to January 1, 1970, and such use and consideration thereof by Deft. without Pltff's express written permission is unlawful; and It Is Further Ordered, Adjudged and Decreed that Deft., his officers, agents, employees and representatives be and they are hereby Permanently Enjoined from any use or consideration for or disclosure to any other person, other than to representatives of other agencies of offices of the U.S. Government including the Committees or Houses of the U.S. Congress, of Pltff's information, research and test data, whenever submitted to Deft. or his predecessors, unless Deft. shall have first obtained Pltff's express written permission; and It Is Further Ordered, Adjudged and Decreed that none of the aforesaid prevents the Deft. from approving applications for pesticide registrations as permitted under §§ 3(c)(5) and 3(c)(7) of FIFRA in cases where the applicant has submitted to EPA, and relied solely upon, his own data to support his application for registration; provided that any applicant for registration must either submit its own data, or cite its own previously submitted data, or cite data that appears in the public literature or cite the previously submitted date of another person with the prior written permission of such other person, and further that EPA is precluded from considering or using any other data in support of any application for registration. (cc: parties)
May 10	Notice of Appeal to the United States Supreme Court, by EPA fld.
May 2	Brief Amicus Curiae In Opposition To Deft's Motion For Stay Pending Appeal, by attys for Amici Curiae fld.
May 2	Statement of Non-Resident Atty, fld.

79-0366C(1) *Monsanto* v. *Costle, et al—Continued*

Date	Proceedings
	5/10/83—Motion For Order Shortening Time for Briefing & Hearings, etc. fld. by AFL-CIO and Natural Resources Defense Council on 5/6/83 submitted to Judge Wangelin.
	5/10/83—Application To Intervene fld. by AFl-CIO & Natural Resource Defense Council on 5/6/83 submitted to Judge Wangelin.
May 13	Transcript of Proceedings, fld.
May 13	Memorandum In Opposition To The Application of the AFL-CIO and NRDC To Intervene, by Pltff. fld
June 2	Order (HKW)—It Is Hereby Ordered that the AFL-CIO and NRDC's motion to intervene be and is Denied. (cc: parties)

In the United States District Court for the Eastern District of Missouri

MONSANTO COMPANY, 800 North Lindbergh Boulevard, ST. LOUIS, MISSOURI 63166

PLAINTIFF

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, 401 M STREET, S.W., WASHINGTON, D.C. 20460,

DEFENDANT

Civil Action No. 79-0366-C(2)

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT, INJUNCTIVE AND OTHER EQUITABLE RELIEF

Plaintiff, by and through its attorneys, for its First Amended Complaint for Declaratory Judgment, Injunctive and Other Equitable Relief, against defendant states as follows:

JURISDICTION

1. This action arises under the Constitution of the United States, including Art. I, § 8, cl. 3 thereof and the Fifth Amendment thereto, under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331(a). The matter in controversy exceeds the sum of $10,000, exclusive of interest and costs.

THE PARTIES

2. Plaintiff, Monsanto Company, is incorporate in the State of Delaware and has its principal place of business in St. Louis County, Missouri. It is licensed to do business in the State of Missouri and resides in this judicial district. It owns and operates, in St. Louis County, Missouri,

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its principal corporate and administrative offices and its major research facilities, including its pesticide products research facilities.

3. Defendant, Douglas M. Costle, is the Administrator of the United States Environmental Protection Agency (hereinafter "EPA"), and is charged with the implementation, administration and enforcement of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 135–136 *et seq.* (hereinafter "FIFRA"). Defendant is sometimes hereinafter referred to as the "Administrator".

NATURE OF ACTION

4. Count I of this action is brought to restrain and redress the deprivation of plaintiff's civil and property rights secured to it by the Constitution and the Laws of the United States. Specifically, this action is brought to declare the illegality and unconstitutionality of the defendant's consideration and use for and disclosure to any third party of plaintiff's property consisting of its trade secret and confidential information, research and test data which it has submitted and will submit to defendant (and predecessor governmental agencies); to declare the illegality and unconstitutionality of Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the Federal Pesticide Act of 1978, Pub. L. No. 95–396 (September 30, 1978); to prevent, enjoin and restrain the unlawful deprivation and taking by said amended provisions of plaintiff's liberties, rights and property secured to it by the Constitution of the United States; and to prevent, enjoin and restrain defendant's unlawful consideration and use for, and disclosure to any third party of plaintiff's property, consisting of its trade secret and confidential information, research and test data which it has submitted and will submit to defendant (and predecessor governmental agencies).

5. Count II of this action is brought to declare the illegality and unconstitutionality of certain arbitrary, capricious and unlawful actions of the defendant and to prevent, restrain and enjoin defendant from such actions.

THE STATUTORY BACKGROUND

6. Since FIFRA was first enacted in 1947, it has required the registration of all pesticides shipped in interstate commerce. Until 1970, the Secretary of the United States Department of Agriculture (hereinafter "USDA") administered FIFRA. Also, until 1970, the Secretary of Health, Education and Welfare, by and through the Food and Drug Administration (hereinafter "FDA"), was authorized to establish tolerances for pesticide chemicals in or on raw agricultural commodities under Section 408 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 346a. These administrative functions of the USDA and FDA were transferred to EPA in December, 1970, by Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15623 (1970).

7. In order to obtain the registration of a pesticide under FIFRA, an applicant was required to support its application for registration with extensive information, research and test data demonstrating that the pesticide was effective for its recommended uses, and that it would perform its intended functions without unreasonable adverse effects on man, vertebrate animals and desirable vegetation. If use of the pesticide for which registration was sought could result in residues in or on raw agricultural commodities, the applicant was also required to submit in support of its application for registration extensive information, research and test data relating to the proposed application of the pesticide, its toxicity, the manner in which it was metabolized, its degradation, and its residues. This data was also required to be submitted in a petition for a tolerance for the pesticide for which registration was sought.

8. In October, 1972, FIFRA was amended by the Federal Environmental Pesticide Control Act of 1972, 86 Stat. 973. Pursuant to this amendment, the registration requirements were extended to pesticides shipped in intrastate commerce and authority was provided for the classification of pesticides and the regulation of their use. The requirements for information, research and test data to

be submitted by an applicant for registration were retained, and, in addition, further requirements were imposed calling for the submission of information, research and test data to assess any risk to the environment which might result from any pesticide for which registration was sought.

9. The 1972 amendment of FIFRA authorized the Administrator in Section 3(c)(1)(D) of FIFRA to use and consider information, research and test data submitted by a previous applicant for registration to support the applications of subsequent applicants, but only upon satisfaction of either of two preconditions. An owner's data could be considered by the Administrator for the benefit of another only if the owner first granted his permission or if the person for whose benefit the data would be used agreed to pay reasonable compensation to the owner. If the parties could not agree as to compensation, the Administrator was authorized to determine such compensation, subject to judicial review. If, however, any of the data to be considered contained or related to trade secrets or other information protected from disclosure by Section 10(b), then without the owner's permission it could not be used at all.

10. Section 10(b) of FIFRA, as amended in 1972, prohibited the disclosure of any information, research and test data of an applicant which contains or relates to trade secrets or other confidential or privileged commercial or financial information.

PLAINTIFF'S DATA

11. Plaintiff has engaged in research and development activities with respect to agricultural and other pesticides for many years. It has played a leading role in the development of agricultural herbicides which are safe and effective.

12. for many years prior to December, 1970, pursuant to the requirements of FIFRA, plaintiff submitted substantial information, research and test data to the USDA and the FDA in support of many applications for registra-

tion of pesticides under FIFRA and petitions for tolerances. Since December, 1970, through the present, it has submitted and will in the future submit substantial information, research and test data to the EPA for these purposes, which submissions have been and will be made pursuant to the requirements of FIFRA.

13. On the basis of the information, research and test data submitted by it, plaintiff has obtained registrations under FIFRA for many pesticide products, most of which are currently produced and sold by it and for which it has developed substantial domestic and foreign markets. Plaintiff has submitted under FIFRA to defendant or defendant's predecessor agencies information, research and test data with respect to the following products:

Product name	Active pesticide ingredient	Active ingredient common name.
Avadex*	S-(2, 3-Dichloroallyl)-diisopropylthiocarbamate.	Diallate.
Avadex* Granular.	S-(2, 3-Dichloroallyl)-diisopropylthiocarbamate.	Diallate.
Avadex* BW...	S-(2,3,3-Trichloroallyl)-diisopropylthiocarbamate.	Triallate.
Far-Go*	S-(2,3,3-Trichloroallyl)-diisopropylthiocarbamate.	Triallate.
Machete*.....	2-chloro-2', 6'-diethyl-N-(butoxymethyl) acetanilide.	Butachlor.
Far-Go* Granular.	S-(2,3,3-Trichloroallyl)-diisopropylthiocarbamate.	Triallate.
Lasso*	2-chloro-2', 6'-diethyl-N-(methoxymethyl) acetanilide.	Alachlor.
Lasso* II.....	2-chloro-2', 6'-diethyl-N-(methoxymethyl) acetanilide.	Alachlor.
Niran* 6-3.....	0, 0-diethyl 0-p-nitrophenyl phosphorothioate; 0, 0-dimethyl 0-p-nitrophenyl phosphorothioate.	Parathion; Methyl Parathion.
Parathion Technical.	0, 0-diethyl 0-p-nitrophenyl phosphorothioate.	Parathion.

Product name	Active pesticide ingredient	Active ingredient common name.
Methyl Parathion.	0, 0-dimethyl 0-p-nitrophenyl phosphorothioate.	Methyl Parathion.
Polaris*	N, N-bis-(phosphonomethyl)-glycine.	Glyphosine.
Ramrod*/ Atrazine.	2-chlorop-N-isopropylacetanilide; 2-chloro-4-(ethylamino)-6-(isopropyl-amino)-s-triazine.	Propachlor/ Atrazine.
Ramrod* 20 Granular.	2-chloro-N-isopropylacetanilide.	Propachlor.
Ramrod* 65	2-chloro-N-isopropylacetanilide.	Propachlor.
Randox*	2-chloro-N, N-diallylacetamide..	Allidochlor.
Randox* Granular.	2-chloro-N, N-diallylacetamied..	Allidochlor.
Roundup*.....	Isopropylamine salt of N-(phosphonomethyl) glycine.	Isopropylamine Salt of Glyphosate.
Vegadex*	2-chloroallyl diethyl-dithiocarbamate.	Sulfallate.
Vegadex* Granular.	2-chloroallyl diethyldithio-carbamate.	Sulfallate.
Rogue*.....	3', 4'-dichloropropionanilide.....	Propanil.
Plus-de-Ris*	3', 4'-dichloropropionanilide.....	Propanil.
Santophen* 1 Germicide.	Ortho-benzyl-parachlorophenol.	Chlorophene.
Santophen* 1 Solution.	Ortho-benzyl-parachlorophenol.	Chlorophene.
None	3, 4, 4' trichlorocarbanilide	Trichlocarban.
ACL* 56 Sanitizer and Bleaching Compound.	Sodium dichloro-s-triazine trione dihydrate.	Sodium dichloroisocyanurate dihydrate.

Product name	Active pesticide ingredient	Active ingredient common name.
ALC* 59 Santizer and Bleaching Compound.	Potassium dichloro-s-triazine trione dihydrate.	Potassium dichloroisocyanurate dihydrate.
ACL* 60 Sanitizer and Bleaching Compound.	Sodium dichloro-s-triazine trione.	Sodium dichloroisocyanurate.
ACL* 66 Sanitizer and Bleaching Compound.	(Monotrichloro) tetra- (Monopotassium dichloro)-penta-s-triazine trione.	(Monotrichloro) tetra- (Monopotassium dichloro)-pentaisocyanurate.
ALC* 85 Sanitizer and Bleaching Compound.	Trichloro-s-triazine trione.....	Trichloroisocyanuric acid.

*Registered Trademark of Monsanto Company.

14. Plaintiff has spent and currently spends multi-millions of dollars annually in research and development activities to develop, maintain and expand its registered pesticide products. To conduct these research and development activities, plaintiff presently employs more than 450 personnel, the majority of whom have advance degrees in chemistry, one of the biological sciences, agronomy or plant physiology.

15. The direct historical cost incurred by plaintiff to develop the information, research and test data submitted by it under FIFRA to secure and maintain the registration of its products is in excess of 100 million dollars. The development by others of the information, research and

test data submitted by plaintiff would be extremely difficult, if at all possible, and would require the highest exercise of sophisticated scientific expertise and ingenuity for thousands of man-years together with the expenditure of enormous sums of money. Most of this information, research and test data is and has been confidentially maintained by plaintiff and stringent security measures are taken to preserve its secrecy. Most of this information, research and test data has not been disclosed by plaintiff except in condfidence to EPA and other governmental agencies pursuant to their regulatory requirements, and heretofore its confidentiality has been preserved by these agencies.

16. This information, research and test data is used by plaintiff in the development of additional formulations for its registered products and in the development of new products which are chemically related to products previously develped by it. It has substantial and incalculable continuing value to plaintiff and affords it a significant competitive advantage in the conduct of its business.

17. By developing this information, research and test data, plaintiff, as owner thereof, has acquired and will continue to acquire trade secrets and confidential commercial interests therein. [Not in development, but in maintenance.]

18. The use and consideration for or disclosure to any third party by defendant of this trade secret and confidential information, research and test data will irreparably injure plaintiff in the conduct of its business, and will confer an immediate and substantial competitive advantage upon its competitors by advancing significantly the state of their technology and by permitting the registration of their products, both in the United States and in foreign countries, without incurring the enormous costs of research and development.

COUNT I

19. Plaintiff incorporates herein and realleges paragraphs 1 through 18 of this First Amended Complaint.

20. Section 2 of the Federal Pesticide Act of 1978 (hereinafter "FPA") amends Sections 3(c)(1)(D) and 3(c)(2) of FIFRA, and Section 15 of the FPA amends Section 10 of FIFRA.

USE AND CONSIDERATION OF PLAINTIFF'S DATA

21. Section 3(c)(1)(D) of FIFRA, as amended by the FPA, makes plaintiff's property, that is, all of the valuable information, research and test data which plaintiff has submitted and will in the future submit, including its trade secrets and other confidential commercial information, available for use by plaintiff's competitors in obtaining pesticide registrations, without plaintiff's permission. This Section, as amended, takes plaintiff's property for private purposes and without just compensation.

22. The allegations set forth in paragraph 21 are predicated upon the Administrator's intepretation of FIFRA as authorizing him to use and consider information, research and test data submitted by plaintiff prior to January 1, 1970, in support of the applications of plaintiff's competitors without compensation to plaintiff for such use. Information, research and test data submitted by plaintiff subsequent to December 31, 1969, may, with certain exceptions, be used and considered by the Administrator for this purpose upon an applicant's mere "offer to compensate", with said applicant's registration to be granted even though compensation for such use may not have been paid or even determined.

23. Section 3(c)(1)(D) also provides binding arbitration procedures respecting this taking and deprivation of plaintiff's property which are devoid of any standards for determining the amount of compensation and expressly deny plaintiff recourse to the Courts. It compels plaintiff's submission to such procedures without plaintiff's prior agreement or consent. If plaintiff does not submit to or participate in these procedures, it forever forfeits any compensation whatsoever.

DISCLOSURE OF PLAINTIFF'S DATA

24. Section 3(c)(2)(A) of FIFRA, as amended by the FPA, requires the public disclosure of most of plaintiff's valuable information, research and test data it has submitted, including its trade secrets and other confidential commercial information, without plaintiff's permission and without affording plaintiff any notice of or opportunity to be heard in opposition to it.

25. Sections 10(b) and 10(d) of FIFRA, as amended by the FPA, permit the public disclosure of plaintiff's valuable information, research and test data it has submitted, including its trade secrets and other confidential commercial information, without plaintiff's permission and without affording plaintiff any notice of or opportunity to be heard in opposition to it.

26. Sections 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the FPA, compel the disclosure to the public and to plaintiff's competitors of plaintiff's trade secrets and confidential commercial information, thereby irrevocably destroying their value and plaintiff's property in them.

ILLEGALITY OF CHALLENGED PROVISIONS

27. Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the FPA, wholly deprive plaintiff of its property rights in and to the trade secret and confidential information, research and test data it has submitted under FIFRA. These Sections, as amended, are unconstitutional in that they are beyond any power conferred on the Congress by Article I, § 8, cl. 3 of the Constitution and are violative of the Fifth Amendment in that they deprive plaintiff of its property and liberty of contract without due process of law, take its property without just compensation and for a private purpose, deny to plaintiff equal protection of the laws, and deprive plaintiff of its right to a judicial determination of the value of property taken from it. Unless Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the FPA, are declared unlawful and their operation and execution preliminary

and permanently enjoined, plaintiff's business will be irreparably injured, its Consitutional rights and liberties irrevocably impaired, and its property destroyed. Plaintiff has no other adequate remedy to prevent the unconstitutional excesses and deprivations effected by these amendments.

RELIEF REQUESTED

WHEREFORE, plaintiff prays for and requests the following relief:

1. That the Court enter its Declaratory Judgment declaring that Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) 10(d) of FIFRA, as amended by the FPA, are unconstitutional and unlawful in that they are beyond any power conferred on the Congress by Art. I, § 8, cl. 3 of the Constitution of the United States and are in violation of the Fifth Amendment thereto;

2. That the Court grant plaintiff equitable relief and enter its judgment restraining and enjoining, preliminarily and permanently, the defendant, his officers, agents, employees and representatives from the implementation and enforcement, in any manner, directly or indirectly, of Sections 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of FIFRA, as amended by the FPA;

3. That the Court grant plaintiff equitable relief and enter its judgment restraining and enjoining, preliminarily and permanently, the defendant, his officers, agents, employees and representatives from any use or consideration for or disclosure to any other person of any of plaintiff's trade secret and confidential information, research and test data, whenever submitted, unless defendant shall have first obtained plaintiff's express written permission; and

4. That the Court grant plaintiff such other and further lawful and equitable relief as may be just and proper.

COUNT II

In the alternative to that part of the relief requested in Count I pertaining to the Administrator's use and consideration of plaintiff's information, research and test data submitted prior to January 1, 1970, and without prejudice to plaintiff's entitlement to the relief otherwise requested by plaintiff in Count I, plaintiff for its Count II, states as follows:

1. Plaintiff incorporates herein and realleges paragraphs 1 through 18 of this First Amended Complaint and paragraph 20 of Count I of this First Amended Complaint.

2. If Section 3(c)(1)(D) of FIFRA, as amended by the FPA, does not authorize or require the defendant to use or consider in support of another person's application for registration any of the information, research and test data submitted by plaintiff prior to January 1, 1970, such use and consideration by defendant is illegal and unconstitutional. Unless the relief sought herein is granted, defendant will use and consider in support of the applications for registration of plaintiff's competitors, the information, research and test data submitted by plaintiff prior to January 1, 1970, without plaintiff's permission and without any compensation to plaintiff whatsoever.

3. The defendant's use and consideration in support of another person's application for registration of plaintiff's information, research and test data submitted prior to January 1, 1970, is illegal in that such use and consideration (a) arbitrarily, capriciously and unlawfully deprives plaintiff of its rights to prevent the unauthorized use by others of its proprietary information, research and test data, including its trade secrets and confidential commercial information, and (b) unconstitutionally deprives plaintiff of its property without due process of law and constitutes a taking for private purposes and without just compensation, all in violation of the Fifth Amendment.

4. Unless defendant's use and consideration in support of another person's application for registration of plain-

tiff's information, research and test data submitted prior to January 1, 1970, is declared unlawful and he is enjoined therefrom, plaintiff's proprietary interests therein will be irrevocably impaired and its business irreparably injured. Plaintiff has no adequate remedy at law or through any administrative procedure to prevent the unlawful and unconstitutional deprivation by defendant of plaintiff's rights in its information, research and test data submitted prior to January 1, 1970.

RELIEF REQUESTED

WHEREFORE, plaintiff prays for and requests, in the alternative, the following relief with respect to its information, research and test data submitted prior to January 1, 1970, and without prejudice to plaintiff's entitlement to the relief otherwise requested by plaintiff in Count I:

1. That the Court enter its Declaratory Judgment declaring that Section 3(c)(1)(D) of FIFRA, as amended by the FPA, does not authorize or require the defendant to use or consider in support of another's application for registration plaintiff's information, research and test data submitted prior to January 1, 1970;

2. That the Court enter its Declaratory Judgment declaring that the defendant's use and consideration in support of another's application for registration of plaintiff's information, research and test data submitted prior to January 1, 1970, is unlawful;

3. That the Court grant plaintiff equitable relief and enter its judgment restraining and enjoining, preliminarily and permanently, the defendant, his officers, agents, employees and representatives from any use or consideration in support of another's application for registration of plaintiff's information, research and test data submitted prior to January 1, 1970, unless defendant shall have first obtained plaintiff's express written permission, and

4. That the Court grant plaintiff such other and further lawful and equitable relief as may be just and proper.

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Attorneys for Plaintiff, Monsanto Company.

CERTIFICATE OF SERVICE

This is to certify that the foregoing was served by placing copies thereof in the United States Mail, postage prepaid, this 30th day of May, 1979, addressed to: Stephen D. Ramsey, United States Department of Justice, Room 1732, Washington, D.C. 20530 and Ann Travis, Assistant United States Attorney, U.S. Court & Customs House, 1114 Market St., St. Louis, Missouri 63101, attorneys for defendant, Douglas M. Costle.

Thomas L. Croft.

In the United States District Court for the Eastern District of Missouri

(Civil Action No. 79-0366-C(2))

MONSANTO COMPANY, 800 NORTH LINDBURGH BOULEVARD, ST. LOUIS, MISSOURI 63166, PLAINTIFF

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, 401 M STREET, S.W., WASHINGTON, D.C. 20460, DEFENDANT

Defendant's Answer

Now comes Douglas M. Costle, Administrator of the United States Environmental Protection Agency, and makes his answer to plaintiff's first amended complaint as follows:

FIRST DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

SECOND DEFENSE

Count II of plaintiff's complaint is not ripe and there is no case or controversy underlying this claim.

THIRD DEFENSE

Defendant answers *seriatim* the numbered paragraphs of plaintiff's complaint.

1.) Defendant admits the Court has jurisdiction of plaintiff's claim.

2.) Admitted.

3.) Admitted.

4.) Paragraph 4 of plaintiff's complaint contains a summary of its allegations and states the "Nature of [plaintiff's] Action." To the extent this paragraph contains any factual allegations, it is denied.

5.) Paragraph 5 of plaintiff's complaint contains a summary of its allegations and states the "Nature of [plain-

tiff's] Action." To the extent this paragraph contains any factual allegations, it is denied.

6.) Admitted.

7.) Admitted that initial registrations for specified uses of products containing particular active ingredients under FIFRA as enacted in 1947 required the type of data support outlined in paragraph 7 of plaintiff's complaint. However, subsequent registrations of products with the same active ingredient and the same use as a product already registered were not required to be supported by the type of data submission alleged by plaintiff. Instead, the Agency's predecessors regularly considered data submitted by one registrant in support of another, subsequent application for registration from any person for a product containing the same active ingredient and used for the same purpose as that already registered.

8.) FIFRA was also amended in 1975 by Pub. L. 94-140; and 1978 by Pub. L. 95-396. These different versions of FIFRA will be referred to as '72 FIFRA, '75 FIFRA and '78 FIFRA. Defendant admits the first two sentences of paragraph 8 of plaintiff's complaint. Defendant denies the remainer of paragraph 8.

9.) Admitted as to the 1972 and the 1975 versions of FIFRA.

10.) Admitted as to the 1972 and the 1975 versions of FIFRA.

11.) Defendant admits the allegations contained in the first sentence of paragraph 11 of plaintiff's complaint. Defendant admits that plaintiff has obtained registrations for agricultural herbicides. Defendant lacks knowledge sufficient to admit or deny the remaining allegations of paragraph 11 of plaintiff's complaint.

12.) Defendant admits the allegations contained in paragraph 13 of plaintiff's complaint, except as to the future actions of plaintiff, which are unknown to defendant and which defendant lacks knowledge sufficient to admit or deny.

13.) Defendant admits that plaintiff has submitted to defendant, U.S.D.A. and the F.D.A. information, research and test data with respect to the products listed in paragraph 13 of plaintiff's complaint. Defendant further admits that plaintiff has obtained registrations for many pesticide products and sells them both in the United States and in foreign countries.

14.) Defendant admits that plaintiff has spent and currently spends substantial amounts of money in the research and development of pesticide products and employs persons to engage in such activities. Defendant is without knowledge sufficient to admit or deny the exact amount of money spent on or persons employed by plaintiff to engage in research and development of its pesticide products.

15.) Defendant lacks knowledge sufficient to admit or deny the allegations contained in the first, third and fourth sentences of paragraph 15 of plaintiff's complaint. Defendant denies the allegations contained in the second sentence of this paragraph.

16.) Defendant lacks knowledge sufficient to admit or deny the allegations contained in paragraph 16 of plaintiff's complaint.

17.) Denied.

18.) Denied.

COUNT I

19.) Defendant incorporates and here realleges his responses to paragraphs 1-17 of plaintiff's complaint.

20.) Admitted.

21.) Defendant disagrees with and denies the inaccurate and incomplete legal conclusion contained in paragraph 21 of plaintiff's complaint.

22.) Defendant is not required either to admit or deny the statement contained in the first sentence of paragraph 22 of plaintiff's complaint. The legal conclusions contained in the second sentence of this paragraph is incomplete and misleading. Section 3(C)(1)(D)(i) and (ii) of FIFRA, as amended by the Federal Pesticide Act of 1978,

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authorizes the Administrator of EPA to consider data submitted by one data submitted in support of a third party's subsequent application for registration of a pesticide product under certain circumstances.

a.) Data submitted prior to December 31, 1969. It is defendant's position that he may consider such data in support of third party applications for registration without the permission of the original data submitter and without requiring an offer of compensation to be made to the original submitter. See Section 3(C)(1)(D)(iii).

b.) Data submitted after December 31, 1969, in support of a registration granted on or before September 30, 1978. It is the Administrator's position that he may consider data submitted during this time in support of third party applications with the permission of the original submitter only if an offer of compensation has been made to the original data submitter. The original submitter's right to compensation is limited to a fifteen year period after the expiration of which the Administrator may use the data without permission of the original submitter and without requiring an offer of compensation to the original submitter. See Section 3(C)(1)(D)(ii).

c.) Data submitted in support of registrations granted after September 30, 1978. Section 3(C)(1)(D)(i) provides that the Administrator may not, without the written permission of the original data submitter, consider such data to support an application of another person during a period of ten years following the date the Administrator first registers a pesticide. The "exclusive use" provisions of sec. 3(C)(1)(D)(i) do not apply to "defensive data." After such ten year period the Administrator may use the data without the permission of the original data submitter subject to the compensation provisions of Sec. 3(C)(1)(D)(ii). See paragraph b above. Concurrently with this ten year period, Sec. 3(C)(1)(D)(ii) provides that for fifteen

years after the date the data was originally submitted the Administrator may consider such data in support of an application by any other person only if such person has made an offer to compensate the original data submitter. Thus, the Administrator may consider "non-defensive" data to support a third party application for registration during the ten year period following its submission only if a.) he has the permission of the original submitter to do so in accordance with Sec. 3(C)(1)(D)(i) and b.) the original submitter has received an offer of compensation from the applicant desiring to rely on data in accordance with Sec. 3(C)(1)(D)(ii). For the next five year period, an offer to compensate the original submitter is the only restriction on the Administrator's use of the data to support another person's application for registration. Thereafter, the Administrator may consider such data in support of third party applications for registration without permission and without requiring an offer to compensate the original submitter.

23.) Defendant admits that Sec. 3(C)(1)(D) provides for binding arbitration in the event the parties cannot agree on terms for compensation for the use of an original submitter's data. Defendant further admits that the failure by an original data submitter to participate in a procedure for reaching an agreement or in an arbitration agreement or failure to comply with the terms of an agreement or arbitration decision concerning compensation under Sec. 3(C)(1)(D)(ii) will result in the forfeiture of the original submitter's right to compensation for the use of the data in support of the application. Defendant admits that, except upon a showing of fraud, misrepresentation or other misconduct by one of the parties to the arbitration or the arbitrator, the findings and determination of the arbitrator shall be final and not judicially or adminstratively reviewable. Defendant denies the remainder of the allegations contained in paragraph 23 of plaintiff's complaint.

COUNT II

24.) Defendant disagrees with and denies the incomplete and inaccurate legal conclusion contained in paragraph 24 of plaintiff's complaint.

25.) Defendant disagrees with and denies the incomplete and inaccurate legal conclusion contained in paragraph 25 of plaintiff's complaint.

26.) Defendant disagrees with and denies the incomplete and inaccurate legal conclusion contained in paragraph 26 of plaintiff's complaint.

27.) Denied.

Wherefore, defendant requests the Court to deny plaintiff all the relief it has requested, to tax costs against plaintiff for general relief.

Respectfully submitted,

ROBERT KINGSLAND,
United States Attorney, Eastern District of Missouri, U.S. Court & Customs House, 1114 Market Street, St. Louis, Missouri 63010.

ANNE TRAVIS,
Assistant United States Attorney.

STEPHEN D. RAMSEY,
Attorney, Pollution Control Section, Land and Natural Resources Division, United States Department of Justice, 10th and Constitution Avenue N.W., Washington, D.C. 20530, 202/633-4160.

Of counsel: Alice Wegman, Edward C. Gray; Pesticides Division, Office of General Counsel, Environmental Protection Agency, Washington, D.C. 20460.

CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of July, 1979, I mailed a copy of the foregoing Defendant's Answer to the following counsel of record:

Lathrop, Koontz, Righter, Clagett, Parker & Norquist; 2600 Mutual Benefit Life Building; 2345 Grand Avenue; Kansas City, Missouri 64108.

Kenneth R. Heineman, Esquire; Coburn, Croft, Shepherd, Herzog & Putzell; Suite 2900; One Merchantile Center; St. Louis, Missouri 63101.

STEPHEN D. RAMSEY.

In the United States District Court for the Eastern District of Missouri, Eastern Division

MONSANTO COMPANY, PLAINTIFF

v.

DOUGLAS M. COSTLE, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, DEFENDANT

Civil Action No. 79-0366-C(1)

FIRST SUPPLEMENTAL STIPULATION OF FACTS

The following facts are hereby stipulated and agreed to by and between the parties herein by their undersigned counsel. These stipulations are for the purpose of this case only and do not constitute admissions of either party in any other case or in any other context:

(1) That much of Monsanto's information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies contains or relates to trade secrets as defined by the Restatement of Torts and confidential, commercial information.

(2) That Monsanto has certain property rights in its information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies which may be protected by the Fifth Amendment to the Constitution of the United States.

LATHROP, KOONTZ, RIGHTER, CLAGETT, PARKER & NORQUIST,

/S/ Joseph E. Stevens, Jr.,

/S/ C. David Barrier,

/S/ Gary S. Dyer,

2600 Mutual Benefit Life Building, 2345 Grand Avenue, Kansas City, Missouri 64108, (816) 842-0820.

COBURN, CROFT & PUTZELL,

/S/ Thomas L. Croft,

/S/ Kenneth R. Heineman,

One Mercantile Center, Suite 2900, St. Louis, Missouri 63101, (314) 621-8575, Counsel for Plaintiff.

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Of counsel: Alice Wegman, Edward C. Gray; Pesticides Division; Office of General Counsel; Environmental Protection Agency; Washington, D.C. 20460; Counsel for defendant.

In the United States District Court for the Eastern District of Missouri, Eastern Division

MONSANTO COMPANY, PLAINTIFF,

v.

ANNE M. GORSUCH, ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY, DEFENDANT

Civil Action No. 79-0366-C(1)

MONSANTO'S PROPOSED FINDINGS OF FACTS

1. Plaintiff, Monsanto Company, is incorporated in the State of Delaware and has its principal place of business in St. Louis County, Missouri. Plaintiff owns and operates its principal corporate and administrative offices, and its major research facilities in St. Louis County, Missouri. It is licensed to do business in the State of Missouri and resides in this judicial district.

(AGREED).[1]

* * * * *

[1] Following those Findings of Fact which plaintiff proposed in support of its Cross Motion for Summary Judgment and to which defendant has agreed, the notation "AGREED" will appear (see defendant's Response to Plaintiff's Proposed Findings of Material Facts). As to those Findings of Fact which plaintiff submitted in support of its Cross Motion for Summary Judgment which are marked "NOT CONTROVERTED", defendant failed to controvert the substantive content of said Findings of Fact, and did in fact state her basic agreement with them, but also except with regard to one such Finding (No. 77) stated that since plaintiff's information to which reference is made in said Findings of Fact is not submitted to defendant under FIFRA as amended in 1978 and thus further is not disclosable thereunder, such Findings of Fact are irrelevant (see Defendant's Response to Plaintiff's Proposed Findings of Material Facts). Plaintiff submits that such uncontroverted Findings of Fact are relevant, and should be entered by the Court herein because they demonstrate the enormous amount of time, money and highly sophisticated scientific effort which must be expended in connection with the development of the information, research and test data which is submitted to defendant pursuant to FIFRA in order to support and maintain the registration of plaintiff's pesticide products, which said information, research and test data will

Continued

15. Plaintiff has engaged in research and development activities with respect to agricultural and other pesticides for many years. For many years prior to December, 1970, plaintiff submitted substantial information, research and test data to the USDA and the FDA in support of many applications for registration of pesticides under FIFRA and petitions for tolerances. Since December, 1970, through the present, it has submitted substantial information, research and test data to the EPA for these purposes.

(AGREED).

16. On the basis of the information, research and test data submitted by it, plaintiff has obtained registrations under FIFRA for many pesticide products, most of which are currently produced and sold by it and for which it has developed substantial domestic and foreign markets. Plaintiff has submitted under FIFRA to defendant or defendant's predecessor agencies information, research and test data with respect to the following products:

Product name	Active pesticide ingredient	Active ingredient common name
Avadex*	S-(2,3,-Dichloroallyl)-diisopropylthiocarbamate	Diallate.
Avadex* Granular	S-(2,3,-Dichloroallyl)-diisopropylthiocarbamate	Diallate.
Avadex* BW...	S-(2,3,3-Trichloroallyl)-diisopropylthiocarbamate	Triallate.
Far-Go*	S-(2,3,3-Trichloroallyl)-diisopropylthiocarbamate	Triallate.
Far-Go* Granular	S-(2,3,3,-Trichloroallyl)-diisopropylthiocarbamate	Triallate.

be disclosed pursuant to the 1978 amendments to FIFRA which plaintiff has challenged herein, all of which is demonstrated by the record herein. As to all other Findings of Fact, a citation to particular portions of the transcript of the trial of this case held March 8-12, 1982, and/or citation to particular exhibits introduced therein, or citation to evidence of which the Court can take judicial notice will appear following the notation "Record Reference".

Product name	Active pesticide ingredient	Active ingredient common name
Lasso*	2-chloro-2',6'-diethyl-N (methoxymethyl) acetanilide	Alachlor.
Lasso* II	2-chloro-2' 6'-diethyl-N (methoxymethyl) acetanilide	Alachlor.
Niran* 6-3	0,0-diethyl 0-p-nitrophenyl phosphorothioate; 0,0-dimethyl 0-p-nitrophenyl phosphorothioate	Parathion; Methyl Parathion.
Parathion Technical	0-0-diethyl 0-p-nitrophenyl phosphorothioate	Parathion.
Methyl Parathion	0,0-dimethyl 0-p-nitrophenyl phosphorothioate	Methyl Parathion.
Polaris*	N,N-bis-(phosphonomethyl)-glycine	Glyphosine.
Ramrod*/ Atrazine.	2-chloro-N-isopropylace tanilide; 2-chloro-4-(ethylamino)-6-(isopropyl-amino)-s-triazine	Propachlor/ Atrazine.
Ramrod* 20 Granular	2-achloro-N-isopropylace tanilide; 2-chloro-4-(ethylamino)-6-(isopropylace tanilide	Propachlor.
Ramrod* 65	2-chloro-N-isopropylace tanilide	Propachlor.
Randox*	2-chloro-N,N-diallylacetamide	Allidochlor.
Randox* Granular	2-chloro-N,N-diallylacetamide	Allidochlor.
Roundup*	Isopropylamine salt of N-(phosphonomethyl) glycine	Isopropylamine Salt of Glyphosate.
Vegadex*	2-chloroallyl diethyl dithiocarbamate	Sulfallate.
Vegadex* Granular	2-chloroallyl diethyldithio carbamate	Sulfallate
Machete*	2-chloro-2', 6'-diethyl N(butoxymethyl) acetanilide	Butachlor.
Rogue*	3',4'-dichloropropionanilide	Propanil.
Plus-de-Ris*	3',4'-dichloropropionanilide	Propanil.

Product name	Active pesticide ingredient	Active ingredient common name
Santophen* 1 Germicide.	Ortho-benzyl-parachlorophenol	Chlorophene.
Santophen* 1 Solution	Ortho-benzyl-parachlorophenol	Chlorophene.
None	3,4,4' trichlorocarbanilide	Trichlocarban.
ACL* 56 Sanitizer and Bleaching Compound	Sodium dichloro-s-triazine trione dihydrate	Sodium dichloroisocyanurat dihydrate.
ACL* 59 Sanitizer and Bleaching Compound	Potassium dichloro-s-triazine trione dihydrate	Potassium dichlordisocyanurate.
ACL* 60 Sanitizer and Bleaching Compound	Sodium dichloro-s-triazine trione	Sodium dichloroisocyanurate.
ACL* 66 Sanitizer and Bleaching Compound	(Monotrichloro) tetra (Monopotassium dichloro)-penta-s-triazine trione	(Monotrichloro) tetra-(Menopotassiu dichloro)-penta-.
ACL* 85 Sanitizer and Bleaching Compound	Trichloro-s-triazine trione	Trichloroisocyanuric acid.
Polado*	Sesqui-sodium salt of N-(Phosphonomethyl) glycine	Glyphosate.

*Registered Trademark of Monsanto company.

(AGREED).

* * * * *

18. A company's decision to develop pesticides requires it to make major commitments long before it can antici-

pate developing a commercial pesticide and even longer before it can expect any return on its investment. First, the company must synthesize, test and evaluate candidate pesticides typically for 4 to 8 years before it will identify a commercial candidate. It must then conduct extensive research for at least 6 additional years, including 2 years to obtain registration, before it can anticipate first marketing a product. Generally, a further 4 to 8 years will elapse before that product reaches a point where its costs of discovery, development and commercialization have been recovered. Second, the company must commit to the employment of a large scientific research group representing many disciplines, and to the acquisition of the necessary physical facilities and sophisticated equipment to conduct the intensive research required to assure some reasonable probability of success in discovering and commercializing a candidate pesticide. Third, any such company must commit to the expenditure of $5 million to $15 million annually for several years before it will develop a potential commercial pesticide candidate. Even then, it will not know whether the candidate will become a commercial product until it has conducted further evaluation for an additional four or more years. This further evaluation could dictate that the candidate be rejected at any point during its development, even in the final year of its further evaluation.

(NOT CONTROVERTED).

19. Once a target is selected, a company must devise extremely efficient, unique and technically sound ways of determining what compounds should be synthesized. The Company's chemists are not only concerned with synthesizing new chemicals, but equally important, are concerned with new chemical processes, techniques, and methods of synthesis to facilitate their invention of such new chemicals. Once a company decides that a new area of chemistry might be fruitful, these chemists then proceed to develop and synthesize new compounds in that area of chemistry. These new compounds are referred to

biologists who determine whether they are biologically active and whether they are pesticide candidates. This biological information is crucial in making the difficult technical judgment whether a compound is worthy of further study. The biologists and the chemists then examine and discuss the results to determine which directions, if any, offer further leads. Using the knowledge obtained from these discussions, the chemists synthesize more new compounds in the directions in which leads are expected. This constant dialogue takes place between literally dozens of organic chemists and biologists and is what ultimately produces the lead which results in a new commercial pesticide.

(NOT CONTROVERTED).

20. Decisions on most of the thousands of chemicals synthesized by plaintiff are made after an initial evaluation called a primary screen which allows plaintiff to determine the probability of a compound becoming commercially successful. With most compounds, this probability is virtually zero, and these compounds are rejected.

(NOT CONTROVERTED).

21. The remaining compounds reach the secondary screen, a much more intensive evaluation involving more complex methods of evaluating the compound's chemistry and biological activity. This stage includes studies in the greenhouse, controlled climate rooms, growth chambers, and limited small plot field tests.

(NOT CONTROVERTED).

22. Only about one in one thousand compounds will survive these first two screenings. For those which survive, field tests are carried out in which the chemical is applied under conditions simulating those of actual agricultural use. If plaintiff decides to commercialize a compound, the commitment to do so must be made at this point. Then, a battery of separate but coordinated activities must also be commenced. It must be determined how the compound can be formulated in order that it can be easily, safely and effectively used by the farmer in the

field. The process chemists and engineers must begin planning to determine how the product can be safely and efficiently produced at the lowest cost in million-pound quantities as opposed to the few grams previously made in test tubes. Acute toxicology tests must be conducted to determine if and how the compounds can be safely used. Expanded field work, metabolism and long term toxicology testing must be initiated. All of these interrelated and interdependent activities must progress to completion at the same time in order that one of them does not become a limiting factor in the development program. Thereafter, full research and development programs proceed with the knowledge that unknown factors could at any subsequent point dictate that the candidate compound cannot become a commercial product.

(NOT CONTROVERTED).

23. For the next two to four years, technical managers involved with the candidate compound are faced with the fact that the few compounds surviving the first stages of testing, each representing an intensive effort involving hundreds of man years and millions of dollars of expenditures, must be thoroughly evaluated in order that they can be commercialized safely and efficiently. On the other hand, every additional year that any of these compounds is tested increases the cost of studying that compound exponentially. If the difficult decision to reject a compound early is not made, the cost accelerates and, more importantly, valuable scientific resources will be wasted pursuing a loser rather than a winner.

(NOT CONTROVERTED).

24. The same difficult decisions must be made as to the expanded process engineering which is initiated in order to determine if raw materials are available, if appropriate large-scale synthesis methods can be divised, if it is possible to produce the product in compliance with the various federal and state regulations dealing with manufacturing safety, discharges of waste, discharges of effluents, emissions of air pollutants, and proper industrial hygiene. Ac-

cordingly, long before plaintiff knows whether it has a successful product, its management must commit further millions of dollars to build a plant for manufacturing commercial quantities of the product according to a chemical process which has not yet been proven on large scale, and to produce a compound whose environmental and toxicological characteristics have not yet been finally determined and for which the necessary approvals by defendant to sell will not issue for 5 to 9 years. If commitments to resolve these problems are not made long before definite answers are available, any of these problems could become a limiting factor and delay the commercialization of a compound for several years.

(NOT CONTROVERTED).

* * * * *

26. It is plaintiff's experience that the initial registration of a new pesticide under FIFRA is usually limited to one or a few important uses of the chemical. Further commercial experience with the compound, together with technical data from continued research and experimentation, may result in new ways of utilizing the chemical. Each of these new or expanded uses must be registered under FIFRA. A great deal of plaintiff's research and development activities are directed to expanding the registered uses of its products. These expanded uses can represent a substantial portion of the market potential of the compound. A substantial part of the effort discussed in connection with the development of a new pesticide must be repeated for each succeeding new use. For example, plaintiff's Lasso herbicide was initially registered only for applications to the surface of the soil, mixed in water, for corn and soybeans. Since then, plaintiff has expanded its registration for Lasso under FIFRA to permit its use in up to 200 different ways on corn, soybeans, peanuts, dry beans and a substantial number of other crops. These expanded uses represent most of the present commerical value of Lasso and, in addition, represent more than 60% of the total research and development effort which plain-

tiff has invested in Lasso. Plaintiff identified the target for which Lasso was developed in the mid-1950's, obtained its initial registration for Lasso in 1969, obtained U.S. Patent No. 3442945 covering the compound in 1969, and in 1979 still has substantial research committed to a number of major expanded uses. These various expanded label changes each require from two to six years of research and development in order to complete the requirements for registration established under FIFRA. In many cases, plaintiff is now using methodology, techniques, protocols and equipment that were not even available when Lasso was first marketed, and many of which were developed by plaintiffs specifically to expand the potential uses of Lasso.

(AGREED).

27. In order to support the registration of its products under FIFRA, plaintiff submits to defendant, information, research and test data of the following types: (1) efficacy studies; (2) phytotoxicity studies; (3) metabolism and residue studies; (4) environmental chemistry studies; (5) toxicology studies; (6) fish and wildlife studies; and (7) manufacturing studies and information.

(AGREED).

28. Plaintiff's efficacy testing begins with the application of the pesticide to very small plots under rigorous conditions to determine answers to limited and specific questions. These small plot studies are continued over a number of years. The small plot testing evolves to large scale field tests using farm equipment, under actual farm conditions. An important factor in the commercial success of any pesticide is not only performance under a given set of conditions, but also its consistency of performance over a wide range of conditions. To determine performance consistency, many trials and experiments must be conducted to understand fully the biological properties of the compound under the widest possible range of conditions. Efficacy testing is utilized to determine and assess all possible argicultural and non-agricul-

tural uses of the product, the target species which are controlled or modified, and the proper rates, methods, time, site, and biological effects of application of the product. This information obtained from efficacy tests is used to devise the most effective methods of use by the farmer under the widest range of conditions.

(AGREED).

29. In plaintiff's phytotoxicity testing, it conducts many trials in the greenhouse as well as in the field to determine the safety of the chemical, not only to the crop for which it is intended, but also to adjacent crops and other vegetation which may receive drift particles from the spray of the pesticide, and to crops which may be planted in succeeding years in the same field on which the pesticide was applied. In the development of plaintiff's pesticides, scientists in different areas of the United States conduct experiments on the most sensitive crops in their general area. They apply the pesticide being tested in very small amounts and in different concentrations to simulate drift to these sensitive crops at different times in their development. These crops are then grown to maturity and measurements of quality as well as yield are made to determine what, if anything, would happen to the crops if they were exposed to the pesticide at any time during the growing season. Plaintiff also plants a substantial number of rotational crops in areas where the pesticide is to be used to demonstrate that succeeding crops will not be harmed by any residues of the pesticide applied to the previous crops. All such field experiments extend over several years.

(AGREED).

30. Plaintiff's metabolism studies are conducted to determine what happens to the compound after it is applied. These studies identify and quantify the chemicals into which the compound is converted and establish the sequence of this conversion. These other chemicals, generally referred to as alteration products, include metabolites which result from the processes of a living organism

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upon the pesticide, and degradation products which result from the effects of sunlight and water upon the pesticide. Plaintiff must determine these metabolic and degradation products in the context of the extraordinarily complex bio-chemistry which is characteristic of living things.

(AGREED).

31. To effectively study the metabolic and degradation products, plaintiff employs the use of radiolabeled pesticide compounds which must be synthesized by plaintiff. Radiosynthesis is a special kind of organic synthesis of a pesticide molecule by which known quantities of radioactive atoms are placed at selected points in the pesticide molecule for the purpose of tracing the molecule. Radiocarbon used in radiosynthesis costs $5,000 to $20,000 for each pesticide sample. Because of the expense of this process, microchemistry must be used and the radiosynthesis route must be much more efficient than a typical chemical synthesis route in order to achieve the maximum yield of radiolabeled pesticide molecules.

(AGREED).

* * * * *

33. In conducting metabolism studies on plants, plaintiff applies the radioactive parent compound by treating the foliage or the soil and collects samples at appropriate intervals. Thereafter, the metabolic and degradation products of the parent compound must be extracted from the plant with organic solvents. These extracts are subjected to a complex series of separation, isolation and purification processes to isolate the metabolites in sufficient purity and quantity for instrumental analysis to gain information about the structure of each metabolite. The structure of the metabolite must then be confirmed by synthesizing it in the laboratory and comparing it with the material isolated from the extracts. Similarly complex studies are conducted with respect to animal and soil metabolism.

(AGREED).

34. In its residue analysis research, plaintiff studies the remnants of the pesticide previously applied, either changed or unchanged from the parent compound. These residues can appear throughout the environment, dependent upon the characteristics of the pesticide. The purpose of the residue analysis is to determine how rapidly the pesticide applied to a crop is dissipated as the plant matures and how much of the pesticide is present in the harvested corp. In conducting these residue studies on plants, one acre test plots are located in those regions of the country in which the plant to be studied is grown. The plant is raised according to good agricultural practices and the pesticide is applied to it in the manner which would be recommended as the normal use pattern of the pesticide on the plant. The plant is grown to maturity, and samples are periodically taken after application of the pesticide and when the crop is harvested. Climatic and environmental conditions which may affect the residues of the pesticide such as rainfall, soil temperature, air temperature, and other chemicals applied to the plant are measured as the plant matures. The collected samples are analyzed by a multifaceted, chemical residue analytical method. This method includes extraction techniques, clean-up procedures to purify and isolate the extracted pesticide residue from the natural products occurring in plants, and qualitative and quantitative identification of the pesticide residue by detection techniques such as gas chromatography. Different analytical techniques must be used depending upon the characteristics of the plant to which the pesticide has been applied. All residue analyses are based upon the development of complex analytical methodology capable of detecting residues of a level as low as one part-per-billion. Extraordinarily sensitive equipment and highly trained individuals are essential in applying the extremely refined techniques used in the residue analyses.

(AGREED).

35. When the pesticide is to be applied to crops which will be consumed by animals, plaintiff conducts metabolism and residue analysis studies to determine what remnants of the pesticide will be in the tissues of the animals and in the animal products, such as milk and eggs. When the pesticide is to be applied to crops which may be rotated with other crops, plaintiff conducts metabolism and residue analysis studies to determine whether any residues of the pesticide applied to the initial crops will appear in the subsequent crops. Plaintiff also conducts numerous residue analysis related tests including interference studies to assure that the residue analytical methods for its compounds are not interfered with or distorted by the presence of other pesticides or by natural products; stability studies to determine whether the pesticide residue samples remain stable during freezing or other storage while awaiting analysis; and studies to evaluate the effect of commercial food processing upon residues of its pesticides in or on raw agricultural commodities.

(AGREED).

36. Plaintiff's metabolism and residue studies which it has submitted to defendant in support of the registration of some of its pesticide products include:

(1) Radiosyntheses and ^{13}C studies rating to the synthesis of the ^{13}C and ^{14}C—labeled parent compound and metabolites.

(2) Plant metabolism studies conducted with the ^{13}C and ^{14}C parent compound.

(3) Standard and confirmatory residue analytical methods relating to residues in plants.

(4) Interference studies to determine that the presence of other pesticides or natural products does not interfere with standard residue analytical methods for plants.

(5) Stability studies relating to plant residues to determine that samples for analysis remain stable in frozen or other storage pending analysis.

(6) Residue analysis studies relating to fodder and feeds.

(7) Studies relating to the effects of commercial processing on residues in foods, fodder and feeds.

(AGREED).

37. In its environmental chemistry research, plaintiff determines the degradation of its pesticides in soil, water and air and the movement of the pesticide on or in soil as the result of rainfall or irrigation.

(AGREED).

38. In this environmental chemistry area, plaintiff conducts water stability studies to determine what transformations occur to the pesticide if it should enter a body of water. These studies are conducted with sterilized water under various conditions of temperature and pH to simulate that which might be found in the environment for the purposes of determining whether and what hydrolysis products may be formed by action of the water upon the pesticide molecule. Studies are then conducted by plaintiff with pond water containing microorganisms to determine what metabolites are formed as a result of the activity of the microorganisms upon that pesticide. As in plaintiff's metabolism studies, these pond water studies are conducted with ^{13}C and ^{14}C molecules and involve sampling at regular intervals, followed by the extraction, separation, isolation, and purification and the identification of metabolites.

(AGREED).

39. To determine whether radiation from sunlight transforms the pesticide compound into other chemicals, plaintiff introduces the ^{13}C and ^{14}C pesticide compound onto soil surfaces and into water and air, and radiates it with artificial light resembling sunlight. Any resultant chemicals are then extracted, separated, isolated, purified and identified in the same manner as the degradation products and metabolites in plaintiff's metabolism studies.

(AGREED).

40. Plaintiff also conducts soil runoff and leaching studies, the former to determine the lateral movement of the compound across the soil surface both in amount an distance, and the latter to determine the movement of the compound down into the soil strata.

(AGREED).

41. Plaintiff's environmental chemistry studies which it has submitted to defendant in support of the registration of some of its pesticide products include:

(1) Studies conducted with the formulated product relating to its soil run-off characteristics.

(2) Studies conducted with the ^{13}C and ^{14}C parent compound relating to its soil leaching characteristics.

(3) Studies conducted with either the parent compound or the ^{13}C and ^{14}C parent compound relating to degradation in pond water.

(4) Studies conducted with the parent compound relating to effects on soil microorganisms.

(5) Studies conducted with the ^{13}C and ^{14}C parent compound relating to degradation by photodecomposition.

(6) Residue analysis studies relating to soils.

(7) Stability studies relating to the parent compound in water.

(8) Residue analysis studies relating to water.

(9) Standard and confirmatory residue analytical methods for soils.

(10) Standard and confirmatory residue analytical methods for water.

(AGREED).

42. Plaintiff's toxicology tests are designed to determine the toxic properties of its pesticides, and their effects on or in biological systems. These studies vary in length of time, test animals used, and purpose. They are multi-disciplinary studies which bridge the sciences of biology and chemistry. The ultimate purpose of these tests is to establish the point at which the compound being studied has no adverse effects.

(AGREED).

43. Prior to commencing its toxicology studies, plaintiff must develop an analytical method to evaluate the stability of the compound in the food to be fed to test animals. It is essential to know whether the compound being studied is stable in food and how long it will remain in the food in order to assure that the experimental animals are consuming the intended doses of the compound. Plaintiff must develop such analytical methods for each of its pesticides.

(AGREED).

44. Plaintiff's subchronic feeding studies are utilized to determine short-term toxic effects and the range of dosage levels to be used in its subsequent long-term toxicology studies. These subchronic studies generally involve the exposure of the test animals to the compound being studied for less than one-half of their lifetime. These tests provide the preliminary data essential for designing plaintiff's chronic toxicology studies.

(AGREED).

45. Plaintiff's chronic feeding studies on dogs measure the effects of the compound upon the animals. These studies are conducted with different groups of animals, each group being administered different dosages of the compound in order to determine the chronic toxicology of the compound over a wide range of exposure. Food intake, body weight, effects on blood, urine, and general systemic effects, are measured throughout the period during which these tests are conducted. At completion, each animal is sacrificed, necropsy performed and histopathological examinations of the tissues and organs are conducted.

(AGREED).

46. Plaintiff's chronic feeding studies on rats and mice determine whether the compound induces or causes cancer or other tumor development and whether there are other toxic manifestations in the test animals.

(AGREED).

47. Plaintiff's three-generation breeding studies determine the effects of the compound upon the reproduction potential of the animals, as well as other effects on the number of young produced, their size and longevity, and birth defects. In these studies the compound is administered to male and female rats beginning in prepuberty. The animals are then raised to maturity and mated, and the compound is then administered to their offspring which are again raised and mated. This process is continued through three generations.

(AGREED).

48. Teratogenic studies are also conducted by plaintiff to determine whether the pesticide has any effects on the development of the fetuses of pregnant females, and mutagenic studies to evaluate whether the pesticide has any genetic effects which may be passed on to future generations.

(AGREED).

49. Plaintiff's toxicology studies which it has submitted to defendant in support of the registration of some of its pesticide products include:

(1) Acute oral LD-50 studies conducted on the rat and the rabbit with the technical product.

(2) Acute dermal LD-50 studies conducted on the rat and the rabbit with the technical product.

(3) Acute neurotoxicity studies conducted on the hen with the technical product.

(4) Acute inhalation LC-50 studies conducted on the rat with the technical product.

(5) Skin sensitization studies conducted on the guinea pig with the technical product.

(6) Dermal irritation studies conducted on the rabbit with the technical product.

(7) Eye irritation studies conducted on the rabbit with the technical product.

(8) Acute dermal LD-50 studies conducted on the rabbit with the technical product.

(9) Intraperitoneal LD–50 studies conducted on the rat with the technical product.

(10) Acute oral LD–50 studies on the rat conducted with the metabolites of and impurities in the technical product.

(11) Subacute dermal studies conducted on the rabbit with the formulated product.

(12) Subacute inhalation studies conducted on the rat with the formulated product.

(13) Subacute neurotoxicity studies conducted on the hen with the technical product.

(14) Acute oral LD–50 studies conducted on the rat with the formulated product.

(15) Acute dermal LD–50 studies conducted on the rabbit with the formulated product.

(16) Acute inhalation LC–50 studies conducted on the rat with the formulated product.

(17) Dermal irritation studies conducted on the rabbit with the formulated product.

(18) Eye irritation studies conducted on the rabbit with the formulated products.

(19) Studies relating to residue methods for measuring the parent compound in feeds and evaluating the stability of the parent compound in feeds.

(20) Subchronic oral rat feeding studies conducted with the technical product.

(21) Subchronic oral dog feeding studies conducted with the technical product.

(22) Chronic and oncogenic oral rat feeding studies conducted with the technical product.

(23) Chronic and oral dog feeding studies conducted with the technical product.

(24) Chronic and oncogenic oral mouse feeding studies conducted with the technical product.

(25) Three-generation rat breeding studies conducted with the technical product.

(26) Subacute inhalation studies on the rat conducted with the technical product.

(27) Teratogenic studies conducted on rats and rabbits with the technical product.

(28) Mutagenic studies conducted on the mouse and microorganisms with the technical product.

(AGREED).

50. In its fish and wildlife research, plaintiff conducts numerous studies to determine the effects of its products upon these species. These include bio-accumulation studies conducted with the radioactive parent compound to determine if the pesticide accumulates in the tissue of fish, and studies conducted with the formulated product to determine its effects upon birds under conditions of normal agricultural use.

(AGREED).

51. Plaintiff's fish and wildlife studies which it has submitted to defendant in support of the registration of some of its pesticide products include:

(1) Acute oral LD-50 studies conducted on quail with the technical product.

(2) Acute oral LD-50 studies conducted on ducks with the technical product.

(3) 96-hour LC-50 studies conducted on bluegill with the technical product.

(4) 96-hour LC-50 studies conducted on trout with the technical product.

(5) Oral LC-50 studies conducted on quail with the technical product.

(6) Oral LC-50 studies conducted on ducks with the technical product.

(7) 96-hour LC-50 studies conducted on bluegill with the formulated product.

(8) 96-hour LC-50 studies conducted on trout with the formulated product.

(9) 96-hour LC-50 studies conducted on aquatic invertebrates with the formulated product.

(10) Bioaccumulation studies conducted on fish with the radioactive parent compound.

(11) Simulated field studies conducted on birds with the formulated product.

(12) Reproduction studies conducted with mallard ducks.

(13) Reproductive life-cycle studies on flathead minnows with the technical product.

(14) LC-50 studies on marine and freshwater organisms.

(AGREED).

* * * * *

53. Much of the information, research and test data submitted by plaintiff to the EPA under FIFRA is and has been confidentially maintained by plaintiff, and stringent security measures are taken to preserve its secrecy. Much of this information, research and test data has never been disclosed by plaintiff except to the EPA and to other governmental agencies pursuant to their regulatory requirements. The information, research and test data is kept in a Technical Reports Library which is continuously supervised during business hours and locked during non-business hours. The circulation of these reports among plaintiff's personnel is on a limited need-to-know basis and the circulated reports are maintained under lock and key. Plaintiff's personnel execute confidentiality agreements respecting this information, research and test data. Plaintiff's Agricultural Research Department has extensive security systems, including guards providing twenty-four hour around the clock protection. Much of plaintiff's information, research and test data has been computerized to facilitate rapid retrieval and research. This computerized data can be accessed only by plaintiff's agricultural Research and Development personnel, and most of them can only access those limited portions of the data which are relevant to their areas of endeavor.

(AGREED).

54. Before any information, research and test data compiled or developed by plaintiff may be disclosed to outsiders, including plaintiff's personnel who are not engaged

in agricultural research and development, it is first carefully reviewed and assessed at three different levels of plaintiff's Agricultural Research Department, including the director of such department, and plaintiff's counsel, to assure that plaintiff's confidential commercial information and trade secrets are not disclosed.

(AGREED).

* * * * *

58. Development of plaintiff's information, research and test data by a competitor would be extremely difficult, if at all possible, and in any event would require the exercise of highly sophisticated scientific expertise and ingenuity for thousands of man-years as well as the expenditure of enormous sums of money.

(AGREED).

* * * * *

71. Much of plaintiff's information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies contains or relates to trade secrets as defined by the Restatement of Torts and confidential, commercial information.

(AGREED).

72. Plaintiff has certain property rights in its information, research and test date.

(AGREED).

* * * * *

77. Defendant now has pending before her applications for registration submitted by plaintiff's competitors which will require defendant to use plaintiff's information, research and test date in order to grant them. Unless the relief sought by plaintiff is granted, defendant will use plaintiff's valuable information, research and test data, including information, research and test date which is or contains trade secrets and confidential commercial information to grant these registrations as provided by Section 3(c)(1)(D) of FIFRA and, thereafter, will disclose such information, research and test data to members of the public as provided by FIFRA Section 10, and to the extent

authorized by FIFRA Section 10 to any foreign government, including the Soviet Union and the Eastern Block countries.

(NOT CONTROVERTED).

* * * * *

/S/ W. Wayne Withers,
W. WAYNE WITHERS,
Monsanto Company, 800 North Lindbergh Blvd., St. Louis, Missouri 63166, (314) 600-2851.

LATHROP, KOONTZ, RIGHTER, CLAGETT & NORQUIST,

/S/ Gary S. Dyer
GARY S. DYER.

/S/ C. David Barrier
C. DAVID BARRIER,
2600 Mutual Benefit Life Building, 2345 Grand Avenue, Kansas City, Missouri 64108, (816) 842-0820.

COBURN, CROFT & PUTZELL,

/S/ Kenneth R. Heineman
KENNETH R. HEINEMAN,
Suite 2900, One Mercantile Center, St. Louis, Missouri 63101, (314) 621-8575, Counsel for Plaintiff.

Certificate of Service Omitted in Printing.

Plaintiff's Exhibit 41

[Testimony from *Mobay Chemical Corp.* v. *Costle,* W.D. Pa. C.A. No. 79-591]

[3710] GEORGE G. ROHWER, called as a witness in rebuttal by the plaintiff, being first duly sworn, testified as follows:

DIRECT EXAMINATION

[By Counsel For Plaintiff, Mr. JACOBSON]

* * * * *

[3711] Q. What has been your work experience since your graduation in 1938?

A. I had some temporary jobs, if you want those, but basically in charge of a ranch for a short period of time, worked for the Forest Service for a short period of time, worked in a clothing store for a short period of time.

In 1940 I joined the Department of Agriculture at Gulfport, Mississippi and have worked with the Department of Agriculture since 1940 to the present in various aspects of pesticide control, basically, varied in my responsibilities, of course, through the years.

Q. So, in essence, you have been with the USDA for the past 40 years.

A. Yes, sir.

[3712] Q. Now, you have before you Defendant's Exhibit 2, I believe, which has been identified as a chart of the Pesticide Regulation Division of the USDA. Do you recognize that chart?

A. Yes, sir.

Q. And there is a G. G. Rohwer shown in the top box as I believe it is Acting Director, or is it Director?

A. That is right, Acting Director.

Q. Of the Pesticide Regulation Division. Are you that Mr. Rohwer?

A. Yes, sir.

Q. Would you tell the Court when you came to the Pesticide Regulation Division?

A. Well, I didn't bring my employment record with me, but it was when Dr. Hays left. I was asked to head that division. It was transferred to EPA in I think December of 1970.

Anyway, when it went to EPA, I elected to stay with the Department of Agriculture, so I was there about a year.

Q. So you immediately followed Dr. Hays as Director of the division?

A. Yes.

Q. Now, during the time that you were Director of the Pesticide Regulation Division, did you understand that there was a policy with respect to the use of a company's confidential [3713] data to support the registration of another company's products?

A. I did.

Q. Would you tell us what that policy was?

A. The policy was simply as stated by Dr. Hays, that we considered data of two types; that is, data which was public information, published information, which included for some of the older pesticides a lot of toxicological data that was developed during the War and shortly thereafter for such materials as DDT, and then confidential data, which was the properly of the registrant, whoever that might be.

Q. And in terms of this data that you have identified, would it have been in accordance with the policy or against your policy for a data reviewer to use that to support a second company's application without consent?

A. The policy that was established by Dr. Hays during his tenure was not changed during the time I was there. Confidential data of the company was their data. Public data was readily used by any for registration.

Q. And when you say it was "their data," I take it you mean it would not be used without consent?

A. That is correct.

Q. An if during your tenure as Director such an act did occur, was it done without your knowledge or consent and contrary to the policy as you understood it?

A. That is correct.

Plaintiff's Exhibit 44

[Deposition from *Dow Chemical Co.* v. *Costle,* E.D. Mich C.A. No. 76-10087]

[1] CIPRIANO CUETO, JR., having been called as a witness by Counsel for the Plaintiff, was duly sworn by the Notary Public, and was then examined and testified as follows:

EXAMINATION BY COUNSEL FOR THE PLAINTIFF

By Mr. JACOBSON:

* * * * *

[8] Q. Okay. Doctor, it is primarily the period of time from 1969 to 1972 that we are interested in here today—that was the time of your employment as the Chief Staff Officer for Human Safety with USDA and then EPA. It that correct?

A. That's correct.

Q. Okay. And as Chief Staff Officer, what were the nature of your duties in that position?

A. Well, I guided the efforts of a staff of about 15 to 20 people, as I remember, and each with responsibilities in various areas of chemicals—such as, some in herbicides, some in instecticides, some in disinfectants.

The primary review involved not only human safety, but involved at that time the fish and wild life as it was referred to. But that responsibility I delegated to someone else and concentrated primarily on the human safety evaluation.

I gave guidance in terms of evaluating the data. [9] I gave guidance in terms of evaluating labels and seeing that the labels actually distilled from the data the information—the toxicological information, and presented it in such a way that the label was most easily understood and reflected the precautions that should be taken.

I also was involved in attempting to develop guidelines, which at that time were rather limited in terms of the actual testing itself that was needed for the toxicological information required for registration.

The duties were primarily in keeping up with the toxicological aspects, chronic, acute, sub-acute or sub-chronic effects a chemical may have.

• • • • • •

[11] Q. Okay. I'll try to make clear in any of my questions now when I refer to data, as to whether I'm referring to company data—that which was generated and submitted by a particular company—and the other kinds of data we have referred to—the public literature data and government data.

With respect to what I will call company data, how was that data treated by you and the people working under you in the Human Safety Staff?

A. It was handled as confidential material. In fact, we were supposed to lock the material up, which we did, at the end of the day. It was maintained, except for the working material that we were handling at that particular time—it was kept in locked files.

[12] The material we were handling at the time was put away in our desk, or finally, I had a safe in my office that this material was put into.

Q. Okay. That would be with respect to maintaining the confidentiality of it within your branch, so that other people who would not be authorized to look at it, I take it, would not have it available. Is that correct?

A. That's correct.

Q. Okay. Then, did you have the situation in which company data would be used without permission to support the registration application of another registrant?

A. Not that I am aware of. This was not the policy. The data was used exclusively for the registration for which it was submitted. It was also used for other registrations if the data had been generated by that particular registrant.

There were data that might be considered for purposes of registration. Such data was that which was already in the literature, already quite widely circulated, and so, therefore, one could draw on that data.

We also what was referred to as "old interpretation 18", which contained, actually, a summation of information based on toxicological data for certain [13] compounds that had extensive formulations registered. And, therefore, one could even—from the interpretation 18—wind up with a particular type of label requirement based on the toxicological information that was accepted under interpretation 18.

• • • • •

[19] Q. With no—maybe I should add, without permission. Was it a situation that you are familiar with that occurred within your staff, where they would use one company's data in support of another company's application without permission?

[20] A. Not to my knowledge. If that had occurred, that would have been, I consider, one of my responsibilities in stopping that sort of thing. The data that was submitted by the applicant was the data to be reviewed, and other data could be reviewed if the applicant had obtained permission for that data to be used. And we had a written statement that such action could be taken.

Q. Okay. And was it your understanding that the policy of the Pesticides Regulation Division was that such a use should not occur?

A. I'm sorry?

Q. Was it your understanding that the policy of the Pesticide Regulation Division was that such a use without permission of the other company should not occur?

A. That's correct.

Defendant's Exhibit P

MAY 22, 1970.

Mr. B. J. CARCEAU,
ICI America Inc.
151 South Street
Stamford, Connecticut 06904

DEAR MR. CARCEAU: This is in reply to your letter of May 8, concerning the development of a new alimicide product.

Efficacy data and toxicological data would be required on a new formulation. Since you did not furnish us the details of your proposed product, it is impossible to state what the exact requirements would be. If adequate data is on hand for a formulation further data is not needed.

Until we receive the complete formula and the proposed labeling for a product, we cannot determine the precise data needs to support registration.

Sincerely,

HAROLD G. ALFORD,
Assistant Director for Registration.

[Airmail]

[DEFENDANT'S EXHIBIT Q]

ENVIRONMENTAL PROTECTION AGENCY,
PESTICIDES REGULATION DIVISION,
Washington, D.C., Mar. 1, 1971.

Mr. J. HATTORI,
Sumitomo Chemical Company, Ltd.,
15 5-Chome, Kitahama,
Higashi-Ku, Oska, Japan

DEAR MR. HATTORI: This is in reply to your letter of February 22, 1971, which has been referred to me by Mr. S. A. Hall of the Entomology Research Division.

Enclosed is a registrant's kit which contains copies of the Federal Insecticide, Fungicides, and Rodenticide Act and all pertinent regulations and interpretations of that Act. Also enclosed are copies of the forms necessary to apply for registration of an economic poison.

It is difficult to answer question number 6 in your letter without knowing the specific compound you are interested in registering. If it is a pesticide that is well-known and for which this Division has toxicological and efficacy data on hand, such data would not be required to be submitted. However, if you are interested in registering an unknown chemical, data will be necessary to show that the product is safe and effective when used as directed.

Sincerely,

T. E. ADAMCZYK,
Chief, Registration Branch.

Enclosure: Registration Kit.

[DEFENDANT'S EXHIBIT R]

PESTICIDES REGULATION DIVISION,
November 16, 1971.

WASATCH CHEMICAL COMPANY
Post Office Box 6219
Salt Lake City, Utah 8106
Attention: Mr. John Walrer.

This is in reference to our recent telephone conference regarding compounds whose patents have expired.

The Federal Insecticide, Fungicide, and Rodenticide Act, states that a product must be proven safe and effective when used as directed and that the burden of proof is on the registrant. However, once this Division receives and accepts such data for a particular compound, other registrants may, for other than disinfectant-type products, register that compound without the necessity of repeating efficacy and toxicity testing. The foregoing assumes, of course, that the subsequent formulation are essentially identical to the product originally registered and that the use patterns are the same.

It should be pointed out that H.R. 10729, the new pesticides bill recently reported out of the House Agriculture Committee, contains a provision that data submitted in support of a registration may not, without the original

applicants permission, be used in support of any other registration. If and when the new legislation is enacted, each registrant will be required to develop his own data.

Sincerely,

T. E. ADAMCZYK
Chief, Fungicide-Herbicide Branch.

[DEFENDANT'S EXHIBIT S]

PESTICIDES REGULATION DIVISION,
January 12, 1972.

Mr. J. J. LENZOTTI,
The Sherwin-Williams Company
101 Prospect Avenue, N.W.
Cleveland, Ohio 44101

DEAR MR. LENZOTTI: This is in reply to your letter of December 21, 1971, concerning requirements for registration of a fungicide.

It is impossible to state precisely what information will be required for your proposed product since we have no way of knowing what claims you intend to make, nor do we know the precise formulation of the product. In general, however, if the product is precisely identical to that product by Rohm & Haas and the claims and directions for the product are the same, no efficacy or toxicity data will be required in support of the registration. If, however, your formulation differs in any way or you intend to make additional claims, efficacy and toxicity data may be required to support registration.

Enclosed are copies of forms for new registration. Please note that this Division requires five copies of your complete formula including the percentage of active and inert ingredients by weight. If you do not have this information, you must request your basic supplier to contact this Division with regard to granting permission to use their file in support of your application.

Sincerely,

T. E. ADAMCZYK,
Chief, Fungicide-Herbicide Branch.

Enclosures.

[DEFENDANT'S EXHIBIT T]

PESTICIDES REGULATION DIVISION,
September 29, 1972.

Mr. JOHN E. GEE, 250 DELAWARE AVENUE,
Apollo Chemical Corporation,
Clifton, New Jersey 07014.

DEAR MR. GEE: This is in reply to your letter of September 18, 1972, regarding registration procedures for a proposed microbiocide product.

To obtain registration it is not necessary to submit a sample of your proposed formulation. Please submit five copies of your proposed label as well as five copies of your complete formula, including the percentage by weight of each active and inert ingredient. Enclosed are several new registration forms. If you will refer to the reverse side of these forms, you will note complete instructions on filing for registration.

Concerning required data, if your product is sustantially identical to other products registered with this Agency, it will not be necessary to submit toxicity or efficacy information. However, if your product is unique or if your proposed patterns of use and dosages differ from those previously accepted, we may require toxicity and efficacy data.

Sincerely,

T. E. ADAMCZYK,
Chief, Fungicide-Herbicide Branch.

Enclosure

[DEFENDANT'S EXHIBIT H H]

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, MEETING OF BOARD OF DIRECTORS, PAUMA VALLEY, CALIFORNIA, APRIL 25, 1970

Minutes

Time and place

A meeting of the Board of Directors was held on Saturday, April 25, 1970, at the Pauma Valley Country Club, Pauma Valley, California at 8:30 A.M.

Attendance

Members Present:

Richard H. Wellman, Chairman—Union Carbide Corporation

James G. Affleck—American Cyanamid Company

Charles O. Barnard—Western Agriculturanl Chemicals Association

Parke C. Brinkley—NAC Association

Jack G. Copeland, Jr.—Hercules Incorporated

K. Ross Fitzsimmons—Shell Chemical Company

Edward K. Hertel—Niagara Chemical Division FMC Corporation

Robert J. Hoffman—Miller Chemical Company, Inc.

Charles L. Hovey—Agway, Inc.

Harold H. Howard—Thompson-Hayward Chemical Company

Carlos Kampmeier—Rohm and Haas Company

Edward J. Korbel—Allied Chemical Corporation

Frank McGrane—Western Agricultural Chemicals Association

Robert M. Morris—Velsicol Chemical Corporation

Robert E. Naegele—The Dow Chemical Company

Frank B. Stewart—W. R. Grace & Co.

Herbert F. Tomasek—Chemagro Corporation

J. Drake Watson—Pennwalt Corporation

Members Absent:

T. W. Cleveland, Sr.—Woolfolk Chemical Works, Ltd.

J. Paul Ekberg—Tenneco Chemicals, Inc.

A. Malcolm McVie—Elanco Products Company Div. of Eli Lilly and Company

Otto Sturzenegger—Geigy Agricultural Chemicals Div. of Geigy Chemical Corp.

Others Present:

James C. Hansen, Chairman of Public Relations Committee (part time)—The Dow Chemical Company

• • • • •

[7] *Naegele Committee Report*

(a) *Confidentiality of Registration Data.*—[8] The Board discussed the proposed letter to the Secretaries of Agriculture, Health, Education, and Welfare, and Interior which appears at pages 13-16 of the supplementary material to the agenda. Mr. Hertel reported that the Policy Advisory Committee, after reviewing the proposed letter, adopted the following resolution:

> RESOLVED, That the Policy Advisory Committee recommends to the Board of Directors that the proposals of the Naegele Committee, as set forth at pages 14-17 of the supplementary material to the Agenda, be adopted by the Board of Directors with the proviso that the recommendations of NACRAC that the proposal be referred to the NAC Lawyers Committee for study be followed.

In the discussion of the proposal, it was the consensus that the proposal that research work conducted on one pesticide compound should not be considered in acting upon the registration of another pesticide compound, should not be premised upon a request that such data be considered as confidential but that the proposal more logically is justified on the basis that the biological properties of related or similar pesticide compounds may differ substantially depending upon the method of manufacture. It was suggested that the proposal, as it appears

in quotes at pages 15 and 16 of the supplementary material to the agenda, be changed to read as follows:

> We propose that each application to the U.S. Department of Agriculture for a label registration of a pesticide chemical or formulation shall contain full reports of all investigations carried out by or for the applicant to show the safety and efficacy of the pesticide formulation. This includes full reports on investigations submitted in petitions for residue tolerances. With respect to formulations, such reports may be included in a registration application by reference properly authorized by an original registrant.

• • • • •

[11] On the following pages is reproduced a NACRAC working paper and the Naegele Committee proposal for your consideration.

• • • • •

[13] PROPOSED LETTER TO THE THREE SECRETARIES (AG, HEW, INTERIOR)

Subject: Industry incentives.

The pesticide industry is presently operating in a very unfriendly, if not hostile, public climate, Substantial companies have left the field entirely. Many other companies have ceased all research, while others have cut back drastically. Soaring costs coupled with inelastic demands have reduced profitability to dangerous level.

If we are to cooperate fully with the governmental agencies and at the same time provide the products necessary for a healthy, low cost agricultural industry, a definite understanding and alleviation of these problems should be considered. Otherwise, development will grind to a halt in the United States leaving the field to foreign competitors and/or drastically impair the cost and quality of our food supply.

[14] In view of this, we proposed what we felt to be one of the most necessary actions to facilitate industry devel-

opment of less persistent and less hazardous materials to man and his environment. The background is as follows:

Background

When registration of a pesticide involves use on crops, the manufacturer submits a petition to the USDA and DHEW proposing a residue tolerance on the crop or crops involved. Registrations for non-crop uses are processed by the USDA only. All data submitted are considered confidential by the USDA, DHEW, and any other interested government agency. The research involved in the preparation of these data is by far the largest source of expense in the total research and development process for pesticides. The cost of this work is expected to increase rapidly as additional tests are required to establish ecological safety.

In general, manufacturers do not engage in this development work on new pesticide discoveries unless they are sure of obtaining a strong patent position with the new product. Thus, a relative large number of unpatentable products that are known to have pesticidal activity remain on the shelves of industrial laboratories. Furthermore, the length of time from the discovery of a new product until all of the work necessary for registration is completed, and until registration is obtained, is such that frequently relatively few years of patent life remain. This also makes it less likely that a manufacturer will decide to [15] push ahead with a new pesticide discovery unless it is aimed at a very large market or has a very broad spectrum of activity.

Under present regulations, once a pesticide is registered by the USDA, another applicant with the same product can submit a label identical in ingredient statement, precautionary information, and directions for use. The USDA then issues the second applicant's registration. The submission of data by the second applicant is not required. When DHEW establishes a tolerance for a pesticide residue on a crop or crops, the tolerance becomes public property. Anybody using a particular pesti-

cide, regardless of the source, is free to do so providing that such product and use do not result in a residue greater than the established tolerance.

Defendant's Exhibit PP

AFFIRMATION OF MULTINATIONAL STATUS

Notice to Requesters of information submitted to the Office of Pesticide Programs, EPA, by applicants and registrants under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

This affirmation is required pursuant to EPA Interim Procedures that implement Section 10(g) of FIFRA (7 USC 136h(g)). This section is reprinted in part on the reverse side for reference. Since the law specifically prohibits disclosure of information to employees or agents of Foreign and Multinational Pesticide Producers, the purpose of this affirmation is to establish whether the requester is affiliated with such producers. Since affiliations can change, this affirmation will be required of each requester at the time of each request.

I have requested access to information submitted by an applicant or registrant under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.) to the Environmental Protection Agency. I hereby affirm:

(1) that I do not seek access to the information for purposes of delivering it or offering it for sale to any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or its agents or employees; and

(2) that I will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees.

I am aware that I may be subject to criminal penalties under 18 U.S.C. 1001 if I have made any statement of material facts knowing that

such statement is false or if I willfully conceal any material fact.

NAME

SIGNATURE

DATE RIN

Client, if you are requesting access on behalf of someone other than the organization or Affiliation listed above.

ORGANIZATION

ADDRESS

Return this form to:
Information Services Branch (TS-757)
PSD, Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Defendant's Exhibit CCC

[Deposition of Dexter B. Sharp, Ph.D., taken on behalf of the Defendant.]

• • • • •

[70] [By Counsel for Defendant, Mr. McLaughlin:]

Q. Okay. If we can move on to Exhibit No. 11 which describes the simple apparatus and is entitled, "A Simple Apparatus and Quantitative Method for Determining the Persistence of Pesticides in Soil." Are you familiar with this paper?

A. Yes.

Q. And in this paper it describes a technique relying a carbon 14 labelling, again, of Roundup to determine the degradation of Roundup in soil, is that correct?

A. Yes. That was used as an example. You will notice we also have CDAA and Diallate as a part of this paper, a couple of our older compounds. The reason this paper was published was to, first of all, appropriate a [71] procedure to the scientific procedure—scientific community which is superior to the guideline directions or recipes for determining being degradation in soil and CO_2 evolution because the citations of the literature that the EPA used in the 1975 guidelines and, indeed, I think—well, the 1975 guidelines were from older literature, were extremely cumbersome, and what we wanted to do in this instance was to acquaint our peers in the scientific community as well as the EPA that, "Look, here's a convenient small concise and precise way to answer a question in regard to pesticides, in general, glyphosate."

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Defendant's Exhibit DDD

[Deposition of JACK DENT EARLY]

[4] JACK DENT EARLY was called as a witness and, having been first duly sworn, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR DEFENDANT

By Mr. RAMSEY:

* * * * *

[25] Q. What I'm also interested in, and I think probably what a lot of folks are interested in, is your understanding at the time of the practice of the United States Department of Agriculture in granting registrations to what let's call "Me-Too" registrants. And if I say, "Me-Too" registrants, do you understand what I'm taking about?

A. Yes. If I could clarify that, when you say, "Me-Too," you're talking about a party or a registrant that comes in and gets a subsequent registration on an identical product without permission or without consultation with the original registrant.

Q. That is correct, sir.

A. I'm differentiating that between a number of situations where we in Monsanto at the time would allow a customer who was formulating one of Monsanto's products to utilize our data to register his formulated product.

Q. That's fine.

A. I'd consider that a "Me-Too" situation.

Q. Fine. Let's make that distinction for the record, for the time being anyway.

[26] Were you aware in 1964 or shortly thereafter of the custom and practice of the United States Department of Agriculture in granting "Me-Too" registrations?

A Granting "Me-Too" registrations? I was not aware of any that were being granted at the time, based on our definition of "Me-Too."

Q. When did you first become aware, if you ever did, that the Department of Agriculture was granting such registrations?

• • • • •

[27] A. I am not aware of any "Me-Too" registrations that were granted by USDA. And I'm restricting that to USDA. We're talking USDA, aren't we?

Q. Yes, we are. That is correct. And now I'm not just referring to Monsanto's, to registrations that might be granted that were substantially similar or identical to Monsanto products. I'm talking about you, as the company representative, being generally aware of the overall picture at USDA. You understand that?

A. Yes.

Q. And it's your testimony that you're not personally aware and never became aware that USDA ever issued any "Me-Too" registrations?

[28] A. Well, I'm not personally aware of any, no.

Q. Did you ever have any discussions with any other company representatives or USDA employees or other persons during that period of time, in which you were told or led to believe that "Me-Too" registrations of the kind we discussed were being issued?

A. I don't recall any such discussions.

Q. Let's ask the same question for EPA. Were you aware at any time prior to 1972 that the United States Environmental Protection Agency was issuing what we referred to as "Me-Too" registrations.

A. Prior to 1972?

Q. Yes, sir.

A. I'm not aware of anything prior to 1972.

Q. Are you aware prior to 1972 whether or not USDA or EPA issued registrations to subsequent registrants? In other words, there'd already been a registration granted to some company, and subsequent to the granting of that first registration, another company comes in and seeks to obtain a registration by submitting a label and data which satisfies EPA that the formula of the product for

which they are seeking a registration is identical or similar enough to almost be identical to the product that was previously registered; [29] and those two departments not requiring any further data to grant those registrations?

A. Let me clarify a point here for you, which would, I think, clarify my understanding here.

We've talked about "Me-Too's," based on our definition earlier here. I am talking with respect to "Me-Too's" from the standpoint of proprietary products. And let me clarify that by saying that there were a few commodity products registered with USDA at the time. By this, it's obvious these were products not under any patent coverage, products that had been around for many years, and the number of which had really never been under any patent protection.

I'll use as an example parathion. It was a commodity item and it was also a product that Monsanto manufactured. We had a number of labels for parathion, and other companies also had labels registered for parathion, and from time to time we would seek to upgrade the label by adding new uses or new rates, new methods of application; and it was not uncommon for those commodity products to go in with a label and registration personnel of USDA, if they had accepted that particular rate use on parathion in the past, would accept your label for registration at the same rate on the same insect without requiring additional [30] efficacy data.

So you could upgrade—you get a label like this without supplying data on a commodity.

Q. When you say "label," you mean "registration."

A. Registration, yes.

Q. How is that different in your mind from what we referred to as a "Me-Too" situation?

A. The "Me-Too" situation—and I think it was a very clear distinction over there in USDA at the time in differentiating between what I call "proprietary" and "commodity" items.

I do not know of anyone who attempted to come in—or if they did, I'm not aware of it—and was successful in getting a "Me-Too" registration for a proprietary product.

Obviously, I can only speak for the Monsanto product line.

[55] Q. • • • • •

Are you aware of any practice of the Department of Agriculture during your time as Monsanto's company representative in requiring "Me-Too" registrants to obtain the permission of any previous data submitter to use or ask the USDA to use or rely on that data to obtain a "Me-Too" registration?

A. To register a similar product?

Q. Yes, sir.

A. I don't think I am.

• • • • •

[58] Q. Did you personally, as Monsanto's company representative, or later, as an employee of NACA, play any part in [59] preparing the testimony that was given before Congress in 1971 about the amendments to FIFRA which were enacted in 1972?

A. Yes, I did. Obviously, that was in the capacity with Monsanto.

Q. Yes, sir.

A. Because at that time I was serving—while still with Monsanto I was serving as the chairman of the NACA Washington Representatives' Committee.

Q. What were your responsibilities as the chairman of that committee?

A. In chairing that committee the Association looked to us for input and suggestions on ideas and approaches in the legislative process in our efforts to develop reasonable and fair legislation.

So I was involved, as chairman of that committee, as part of that process.

Q. Did that include developing ideas and proposals about exclusive use provisions to be put into FIFRA?

A. I was part of that process, yes.

Q. What part? Were you just a member, or were you the chairman of the committee that——

A. I was chairman of the Washington Reps' Committee, [60] but I'm not sure that that provision was an initial thought out of the Washington Representatives' Committee, is what I'm saying. That's eight, nine years ago. I just don't recall.

Q. As you now recall it, what was the reason that NACA and Monsanto—no, let be back up.

As Monsanto's representative at the time, do you recall whether Monsanto favored the exclusive use provision that was subsequently put into the 1972 FIFRA?

A. Yes, I'm sure we did.

* * * * *

Defendant's Exhibit FFF

[Deposition of Harry W. Hays Taken in *Dow Chemical Co.* v. *Costle*, E.D. Mich. C.A. No. 76-10087.]

EXAMINATION BY COUNSEL FOR PLAINTIFF

By Mr. JACOBSON:

* * * * *

[6] Q. Okay. In this deposition, Doctor, what we are primarily interested in is your employment experience with the Pesticide Regulation Division of the United States Department of Agriculture.

In that connection, would you indicate how you came to become Director of the Division?

A. Well, it was in 1965, 1965 or very early 1966, that I was asked by the Secretary of Agriculture, Mr. Orville Freeman, if I would be the Chairman of a Task Force to review the activities of the Pesticide Regulation Division, [7] because at that time they were under considerable pressure for improvements, and the Department thought it would be best to appoint a Task Force to take a look at what was taking place.

That committee was formed rather quickly. In a matter of I expect five or six months, maybe a little less, the committee submitted its report to the Administrator of the Agriculture Research Service. and shortly thereafter, I was asked by the Administrator if I would consider taking on the responsibility of being the Director of the Division.

I was then called into Secretary Freeman's office to discuss the possibility of my becoming Director of the Division, and after considerable thought I decided that maybe I could help in reorganizing the Division. So I accepted the offer to become the Director.

* * * * *

[11] Q. Okay. The question, or one of the issues in this lawsuit, Doctor, deals with the treatment of company data [12] by the Pesticide Regulation Division, USDA. And I will separate it into two parts—one dealing with

disclosure and making it available to other people, and the other dealing with use.

First, let me ask you about disclosure. Was the data—company data—let me say confidentially maintained by the Division under your tenure?

A. Well, it was my instruction to the Assistant Director of Registration and to the Assistant Director of Enforcement, that the data that was submitted by the industry was to be considered confidential.

Now, in that light, in addition to the files that we put in under a central file, in order to maintain that integrity of the file and the confidentiality, we also gave each of the reviewers a file, in this case a locked file to keep at his desk where the reviews were being made. And this was totally directed toward maintaining confidentiality.

Q. Okay. Now the other aspect in terms of company data that I want to ask you about, Doctor, and during your time as Director, was a question of use of that data in support of registration applications.

Now, I take it that you would agree that the company [13] who had developed and submitted the data in support of its own registration application, there was no question about the registration—the Regulation Division using that data in the review of their particular application for registration.

A. That is correct. It was used for their sole purpose.

Q. Okay. Are you also aware of situations where a company who had developed and submitted data in support of their applications would grant permission to other applicants, or to the Regulation Division for you to use that data in support of an application for registration by another company?

A. Yes. There were instances when the registrant would permit his data, or her data, to be used for the registration of another product.

Q. Okay. And that—would that, in your judgment, violate any of the policies that were in effect at that time?

A. No, provided that in the use of that data we had direct confirmation by the registrant, either by letter or by phone or whatever it may be, that it was permissible for that person, or for us, to use that data to register the product per that person's request.

[14] Q. Okay. Now, let's take a situation, one in which the Government, or the Defendant has indicated in this case, that it was the regular practice of the Pesticide Regulation Division to use one company's data in support of an application for registration by another company, without permission.

Would any such use have been in accordance with the policy of the Division at the time you were Director?

A. No, it wouldn't.

Q. Okay. What would have been the policy with respect to such a use?

A. Our policy, from the very beginning, was that the data that was—belonged to one individual registrant was not to be used by another unless he had permission.

• • • • •

[23] Q. Okay. And to your knowledge, if any occasions arose in which company data had been used to support an application for registration of another without permission, would that have been in violation of the policy that you had established as Director?

A. It certainly would have.

• • • • •

[29] EXAMINATION BY COUNSEL FOR THE DEFENDANT

• • • • •

[51] A. Well, as the Director, I was responsible for setting the policy and instructing the staff as to what the policies would be, of working out difficulties that might arise from day to day in matters of registration or enforcement, working with them to organize and coordinate the activities of the Division, educational programs for

the staff, just regular day-to-day supervision through the directors, assistant directors.

• • • • •

[52] Q. Would it be fair to say, then, that Mr. Alford would be more familiar with the actual day-to-day operations of the registration program then you, yourself, would be as supervisor?

A. I think so—as Director.

• • • • •

[59] Q. Now, you also stated that it was your policy that one applicant could not rely on data which another applicant had submitted without the first applicant's permission.

A. Correct.

Q. Now, when you are talking about data, are you [60] referring to the confidential statement of formula, or are you referring to all types of data?

A. I'm referring to the formula, I'm referring to the safety data, and I'm referring to the effectiveness data.

• • • • •

[65] Q. Now you testified that you had a policy regarding consideration of one person's data in support of another company's application. Do you know whether, in fact, that policy was followed in the day-to-day issuance of registration?

A. How would I know? I have no idea. I wasn't at every desk day-to-day.

Q. So the answer is no, you don't know whether it was followed or not.

A. No. That's right.

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DEFENDANT'S EXHIBIT GGG

[Deposition of Cleve A. I. Goring Taken in *Dow Chemical Co.* v. *Gorsuch* E.D. Mich., C.A. No. 76-10087]

EXAMINATION BY THE COUNSEL FOR DEFENDANT

By Ms. MULKEY:

* * * * *

[33] Q. Your counsel have listed you as a witness who will support a finding which they proposed the Judge make, to the effect tha' he patent protection is difficult and expensive to secu.' nd maintain in nations other than the United States.

Could you tell us the comparative patent situation between the United States and other nations?

A. Yes.

Q. To your knowledge?

A. Yes. I have spent a great deal of effort on the question of patents and obtaining valid patents. In fact, that's one of the things I've spent quite a lot of time on.

Patent law, of course, varies in all over the world. Some countries you can't obtain patents in, some countries the patents that you do obtain have really relatively little validity or usefulness. For example, in many of the [34] eastern European countries or Russia they are so specific they don't provide a broad frame of protection. Some countries the patent will last for 15 or 20 years, some countries much shorter period of time. In some countries you have to renew your patent franchise every few years, as you pay fees, and in others you do not, like the United States.

In some countries you basically have to work the patent or it lapses. In other words, if you apply for a patent in Spain, then you have to basically work that patent or sell the product or manufacture it within a period of three years or else the patent lapses. So most people simply don't get patents in Spain because in this kind of product, they can't meet the requirements.

But there's one major difference between the United States and virtually all other countries, virtually all countries in the world, Canada is an exception which I will explain. In the United States the person that gets the patent is the first to invent so that if there is an argument about patentability in the United States, and there's an interference, then the case goes before the Patent Board and a determination is made as to who invented it first. So you go back all the way through the dates of original synthesis, original biological testing. But in the rest of the world the person that gets the patent is the [35] first to file a case, and it doesn't matter whether the first to invent or not. So it becomes extremely important in order to get patent coverage in countries around the world that you file quickly.

Those that don't, don't get patents around the world. And so, I must tell you that in 20 or 30 years ago when most of the U.S. companies basically were conducting pesticide business primarily in the United States, rarely overseas, that they would take their time about filing U.S. patents because they knew the first to invent would get the patent. But as the whole patent—as the whole pesticide arena expanded and the U.S. companies moved overseas and other companies moved into the U.S., and I think approximately 65% of the pesticide business is outside of the U.S., it became very important to file early. And so our present policy, and I believe the policy of virtually every company in the business, is to file their cases as early as possible. This means that even before compounds are in development, patent cases are filed now, and probably will become allowed within a year of being in development.

So we have the problem of a very long time before commercialization, but the necessity to file early in order to obtain the patent coverage around the world.

Q. In other nations you mean now?

[36] A. In other nations, yes. I must say, though, that even if you don't file, if you don't file early in the United

States and you get into an interference, you are at a disadvantage, you are not the first to file, you then are the Plaintiff, you have to prove that the person that was first to file isn't entitled to the patent. He's the Defendant, you're the Plaintiff, so he stands back and shoots at you.

Q. Okay. With respect to the patents in other nations, has Dow ever attempted to correlate its sales volume or profit to its degree of patent protection to determine whether the patent availability and quality of patents has affected its market in other nations?

A. Oh, yes, I think so. You have to have patents in the ag business. You either have—you have to have protected products, one form or another. If you do not, the business is so enormously competitive, that unprotected products are apt to become unprofitable.

Q. Could you name a nation which has no patent protection which is a major agricultural nation?

A. I don't—well, Italy is one which it's very difficult to get significant patent protection.

Q. Does Dow market products in Italy?

A. Oh, yes, and we have imitators.

Q. Has Dow determined that its market share in Italy is [37] significantly different than its market share in, say, France?

A. Well, I—that depends on your ability to market in the countries. But I would say that we certainly have more competition from imitators in Italy prior to the time that our patent protection runs out than in France or Britain or Germany.

For example, on the pesticide Plictran, we had imitators selling Plictran in Italy long before the patents on Plictran ran out in Europe. As soon as the patents run out, you ordinarily on a major pesticide will have imitators producing the product.

Q. In most countries?

A. Yes.

Q. And at purely as soon as the patent runs out?

A. Well, you have the worldwide, when the patents run out you will have it in specific countries where you can't get patent coverage before the patents run out.

Q. Pretty much regardless of any other requirements like registration requirements?

A. Now, that's not necessarily so. And I don't know what the situation is in Italy personally; basically most of the major countries, in fact, virtually all of the major countries currently do not permit imitators to utilize the registration data that a company provides for the [38] registration of pesticides in that country.

Q. I'm having a little trouble reconciling these things that you've just said. I take it the key to the big burst in competition in any nation is when the patent protection in that nation expires, is that what I understood you to say?

A. The big burst in competition is when patent expiration takes place all over the world, and that takes place over a period of, perhaps in the major countries, four or five or six or seven years or so.

Q. In nations——

A. If you think of the actual time schedule involved, for example, the window in which you have to operate under a protected situation is relatively small. The reason for that is you get your patent early, just about the time you go into development. It may take you six years, seven years before you start to market; certainly six years. Then your registrations are not achieved all at once, but over a period of time so that you may not achieve full registration of your chemical, I don't know, it may be as long as six to 15 years. Your patent runs out 17 years after it's granted, 15 to 20 years.

So frequently you are still obtaining registrations at the time your patent runs out. Then when your patent runs out, basically imitators will attempt to obtain [39] registrations all over the world and produce the chemical at that time.

Q. And I take it that they've been succeeding and entering into competition against Dow and other companies that held the patents?

A. To some extent, to some extent, yes.

Q. In nations where one or two or three major agricultural companies cultivate the vast bulk of the land, let me, sir, start there. I take it there are nations where that's the case?

A. Where what?

Q. One or two or perhaps three major agricultural companies cultivate the vast bulk of the land, like United Fruit, and in certain Latin American countries, for example.

A. Oh, I don't think they cultivate the vast bulk of the land, but they are certainly, for specific crops they are—what should I say, they are the major economic force for certain specific crops in that country, yes.

Q. Okay. Now, does Dow sometimes enter into contracts, exclusive contracts, for sale to such companies so that, for example, Dow would be the sole supplier of a given pesticide to a given major company of the sort we just discussed?

A. Well, I—I'm not knowledgeable in that area. However, I would guess that those companies don't get into exclusive [40] contracts with anybody, you know, they will purchase their product wherever they can at the lowest price they can.

Q. Does Dow sell at pretty much the same price worldwide for a given product?

A. Oh, no. The price of the product that we sell depends on the value of the chemical in the marketplace, if it's possible to obtain that value. If it's not possible to obtain that value, it depends on the competitive forces in the marketplace.

For example, we sell 2,4-D primarily on a competitive basis with other companies in the marketplace. We don't sell it on the basis of its value in the marketplace which far exceeds its selling price simply because there's too

much competition. But where you have—where you are protected, when I say protected, where you basically have an opportunity to sell your product without competition from an imitator, you sell it at the value in the marketplace or try to sell it based on its value in the marketplace.

Now, that does not mean that you are free from competition because agricultural chemical business is an intensely competitive business just from the introduction of new and better products. In fact, I will say that that is where most of the competition comes from, [41] continual introduction of new and better products.

But it does mean that you can basically sell your product at what you believe is the value in the marketplace rather than selling it at a price that reflects on the competition from imitators that have not had the expenses and the cost and have basically not had to pay the expenses and the cost of developing the product in the first place.

Q. Now, when you say value in the marketplace, do you mean essentially the highest price the market will pay without declining to purchase the product?

A. Yes. And I can tell you what that works out to be because it's—it's a well known measure in the agricultural marketplace. For example, fertilizers are so uniformly accepted by farmers that ordinarily they will pay for—they will expect to receive from their fertilizers in terms of value at least twice of what they paid, so if they expend a dollar on the fertilizer, they will expect to see two dollars in return in terms of production.

Pesticides are not really as well accepted, and so even with a very well accepted pesticide, the farmer would expect to see three dollars of productivity in turn for every dollar expended.

In new products, new developments where the farmer is unsure, the practice is new, he will expect to receive five dollars of productivity in turn for every dollar [42] expended. And if you can provide him with a practice in

which he receives a ten to one return, he will buy it under almost any circumstance.

• • • • •

[57] Q. Okay. So that when one speaks of process research and development, one includes the notion of what kind of tools and assembly line operation and so forth would be designed as well as this category of things contained in that paragraph?

A. Yes. When you talk about process research, what you are talking about is basically all of the research that is needed to indentify the structure and operating conditions of the entire production and waste handling and disposal plan associated with a product, plus the operations to formulate the product, manage it and so on.

Q. Is that fairly complex?

A. Enormously complex, very complex.

Q. It takes a high degree of expertise in order to do that kind of work?

A. Yes, I would say so.

• • • • •

[58] Q.

A. Oh, yes. The production capabilities and experience capabilities of a company are highly dependent on their, what shall I say, their overall collection of knowledge in that area, either in the heads of the people or in company reports, confidential reports, their total experience in that production arena.

• • • • •

Q. And I take it the confidentiality of the research and development associated with process research gives the company an enormous competitive advantage?

A. Well, it gives them a competitive advantage in the sense that it doesn't—the information isn't available to a competitor without doing any work. He can go through the same steps if he's got the capabilities to do so, he can if he puts the energy into it, and is lucky and has good enough people and happens to think along the same directions and is inventive and so on. Presumably he could

come up with the same kinds of information. But the chances are that he would not, not two companies have the same in-house expertise.

DEFENDANT'S EXHIBIT III

[Testimony of Harry W. Hays from *Mobay Chemical Corp.* v. *Costle*, W.D. Pa. C.A. No. 79-591.]

EXAMINATION BY COUNSEL FOR PLAINTIFF

By Mr. JACOBSON:

* * * * *

[3701] Q. Okay, sir. During your tenure as Director, what was your policy, if there was one, with respect to the use of one company's proprietary data to support the registration application of another company's product?

Mr. CAFFERTY: I am going to object to the form of that question, your Honor. I think we should have a definition of what "proprietary" means.

[3702] Mr. JACOBSON: Data supplied to you by a company generated by that company.

A. Let me say that my position was somewhat of an outgrowth of the studies that we had made—that is, the task force—and when I took the position as Director, it was my policy to make sure that no proprietary or let's say any information submitted by any applicant or registrant that was considered to be confidential would be maintained as confidential.

Q. And with respect to the registration——

The COURT: Did you say it was your policy it would be, or it would not be?

The WITNESS: It would be maintained as confidential.

By Mr. JACOBSON:

Q. With particular regard to the registration of another company's product, what was your policy with respect to the use of the company's confidential data in support of another company's application?

A. The staff was required to ask in all instances for information when the application was submitted. They were not permitted to use any data that was submitted by any other registrant for registration purposes.

Q. And would this be in all cases, or just in instances where consent had not been obtained?

A. All cases.

[3703] Q. Dr. Hays, the question I just asked you I'm not sure I made completely clear, so let me ask it again. You testified that your policy was to maintain or not allow the use of one company's data in support of another's application.

A. That is correct.

Q. My question to you was if the first company gave consent to the division to allow the use of another company's application, would that be acceptable?

A. That was permissible.

Q. And we have had some testimony in the case that the division granted applications for registration by a second company on the basis of another company's data. If that did occur, was it done without your knowledge or consent and was it contrary to your policy?

A. It was done without my knowledge and consent and contrary to policy.

• • • • •

[3704] Q. • • • Now, your were up right at the top of the chart. You were the actual Director of the whole Registration Program, including [3705] enforcement, the whole Pesticide Program, including enforcement and registrations; is that right?

A. That is correct.

Q. Who was it when you were Director who was in charge of the Registration Program?

A. Mr. Alfred.

Q. That is Harold Alfred?

A. Harold Alfred was the Assistant Director for Registration.

Q. So he was the one who was in charge actually of that particular Registration Branch?

A. That is correct.

• • • • •

[3706] Q. And you had oversight responsibility over Mr. Alfred and also whoever it was that was in charge of the Enforcement?

A. That is correct.

Q. Now, Mr. Alfred wasn't the one who actually handled the registration when the came in, was he?

A. No. They were first reviewed by other people.

Q. Sure. That was done by people down in the Registration Branch?

A. That is right.

Q. And basically it was the program specialists who were responsible for shepherding the application through the process?

A. That is correct.

• • • • •

[3707] Q. Now, you testified about the policies that you implemented as Director of the Registration or Director of the Pesticide Programs. Were any of these policies regarding what Mr. Jacobson terms the use of data to support someone else's registration written down in the form of regulations or policy statements?

A. Not that I know of any specific details of policy.

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Defendant's Exhibit KKK

[Testimony from *Mobay Chemical Corp.* v. *Costle*, W. D. Pa. C.A. No. 79-591]

[5] HAROLD ALFORD called as a witness by and on behalf of the defendants, being first duly sworn, testified as follows:

[By Counsel for Defendant, Mr. CAFFERTY:]

* * * * *

[8] Q. What was your position immediately prior to 1972?

A. I was Director of the Pesticides Regulation Division.

Q. How long did you hold that position?

A. From April of 1971 through into November of 1972; a little over a year and a half.

Q. And what were your responsibilities when you were in that position?

A. I was responsible for the administration of all the division functions which included the administration of the Federal Insecticide, Rodenticide and Fungicide Act except for the enforcement segment, the enforcement actions under the law.

Q. Was one of your responsibilities then between 1972 and 1972 to oversee the functioning of the registration program?

A. Yes, sir.

Q. All right. Now, prior to April of 1971, were you also employed by EPA?

A. Yes, sir.

Q. And what was your position at that time?

[9] A. I was Assistant Director for Registration of the Pesticides Regulation Division.

Q. And how long did you hold that position?

A. From December of 1966 until April of 1971.

Q. In December 1970 the pesticide registration functions were transferred from the United States Department of Agriculture to the Environmental Protection Agency. Were you the Assistant Director in charge of pes-

ticide registration both at USDA and after its transfer to EPA?

A. Yes, sir.

Q. So essentially, you were in the same position from 1966 to 1971?

A. Yes, sir.

Q. What were your responsibilities as the assistant director in charge of registration?

A. I was responsible for developing operating procedures and policies regarding the registration of pesticides and for overseeing the movement of paper work and the registration process.

Q. Prior to 1966 were you also employed by the United States Department of Agriculture?

A. Yes, sir. I was Assistant to the Director on the staff of the Division Director from 1961 through 1966.

Q. And what were your responsibilities in that position?

A. I had a wide range of staff responsibilities supporting the administration of the division, development [10] of regulations as far as pesticide registration is concerned, development of certain procedures and I edited and published the USDA Summary of Registered Pesticide Uses.

• • • • •

[15] Q. I direct your attention then to 1967 to 1970 when U.S. Department of Agriculture processed pesticide registrations and issued pesticide registrations and let me pose the hypothetical question again. Assume an applicant came in and wanted to register a pesticide product with a brand new active ingredient, one that had not previously registered, what general types of information would the United States Department of Agriculture require that pesticide applicant to submit in support of his application?

A. Well, first he would be required to submit extensive chemistry information on the ingredient and the product. He would be required to submit test data that would enable us to determine safety when the product is used as

directed, determine that the product would be effective and safe to use as directed, and that the directed use would not leave illegal residues on food or feed crops.

Q. So those are the three basic types of questions that you wanted answered by the data submitted by the first applicant?

A. Yes, sir.

Q. Now, suppose a second applicant comes in or came in between 1967 and 1970 and asked for registration for a [16] product that was the same as one that had previously been registered. What type of data did the United States Department of Agriculture require that applicant to submit?

A. If we already had the data on the previous one, the same questions of course would apply as far as effectiveness, safety and residues. If we already had the information to show safety and effectiveness and the absence of illegal residues, we wouldn't require the same data over.

Q. So the second applicant then would not have been required to submit additional data if none was needed?

A. If the original data applied, that's true.

Q. Is the system that you just described the system of registration based on established use patterns commonly referred to as based on established use patterns?

A. Yes, sir.

* * * * *

[19] Q. Did the United States Department of Agriculture as a matter of policy require the applicant to get permission from the data submitter to rely on the data that had been submitted?

A. We did require the submission of a complete statement or formula or authorization to refer to the original submitter's file for formula information, but not for test data.

Q. Now you said you did require permission for the confidential statement of formula. Was that policy written down anywhere?

A. Yes, sir. It was.

* * * * *

Defendant's Exhibit VVV

[Deposition of Nicholas Lee Reding, taken on behalf of the defendant.]

DIRECT EXAMINATION

Questions by Mr. CAFFERTY:

* * * * *

[28] Q. What about the patentability of a chemical, is that an important consideration?

A. Absolutely.

Q. If a chemcial was not patentable, if your patent lawyers said. "Look, we can't get a patent on this chemical," would Monsanto continue to develop that chemical as a pesticide.

A. That would certainly influence our thinking and, of course, it partly comes to the issue at hand. We're in a highly proprietary business and particularly with our unique approach to Europe. A proprietary position is absolutely imperative to use and it's conceivable that if we could not get [29] a patent but we thought that we could protect our innovation by virtue of the data we develop as part of that innovation that we might still make that decision to proceed but without some kind of protection it would be certainly less likely.

Q. And generally patent protection is something that you try to get in every case, would that be fair to say?

A. Yes, and data protection.

* * * * *

[30] Q. Okay. Now, when Monsanto attains a patent, does it just attain a patent in the United States of does it file for patents in other countries as well?

A. We file worldwide as we deem appropriate.

Q. What would be the factors that would influence whether you deemed it appropriate or not?

A. Well, there are a number of countries around the world where you can't get patents today or where there are some questions about the patent system and we would obviously take that into consideration but our gen-

eral approach would be to file for patents wherever we think it gives us some degree of protection.

[31] Q. You said there is a number of countries in which the patent system is not very good. What is the basis for your statement?

A. Well, and you have to deal with it in degrees. There are countries where there is no patent system. The People's Republic of China is a case in point where you can't get patents today. Indonesia is another case in point. There are countries where you can only get a process patent which does not provide much protection since there are typically a number of processes that can be used to make any given compound. India is a case in point.

There are areas where there is question about the likelihood of getting a strong patent for ag-chemicals. The Andean block is a case in point where, in effect, a number of years ago they stopped given pharmaceutical patents and they attempted to look at ag-chemicals in the same way. Also countries where the patent system has not been tested by any jurisprudence at this point so until it is, there is some question about the validity of it. Brazil is a case in point.

So all in all, if you look at Eastern Europe where there are some difficulties, you look at Spain where you can only get process patents, and as I mentioned, the Andean block, Mexico, a number of years ago adopted what they call a certificate of invention which really gives you very [32] little protection. I mentioned Indonesia and India. There are in varying degrees a number of situations where the patent situation either doesn't exist or it's considered to be somewhat weak.

Q. In these countries which you mentioned, and you mentioned a number of countries, what has been Monsanto's experience with respect to the competition which it has faced from other companies selling the same pesticide as yours?

A. I can give you some specific examples. There are a number of countries that make great things of doing these sort of procedures. The Taiwanese are a good case in point and for years it was very difficult to get any kind of meaningful patent coverage in Taiwan and as a result, if you look at a number of major proprietary products in this agricultural chemical area, in some cases there are multiple producers in Taiwan.

Another case in point is in the Eastern block. Hungary, specifically Hungary went through a period where they would reward the inventions of the Hungarian country but not the non-Hungarian countries and, in effect, they are discriminating against non-Hungarian countries and as a result, there are a number of Hungarian countries that have made products that were the inventions of non-Hungarian countries and multinationals.

[33] A third case in point is Israel. In Israel there is a procedure for opposing patent applications and in some cases the Israeli countries have been successful in their opposition by virtue of the local procedures and so there are a number of Israeli companies that are making a lot of these products.

And it's not only a matter of Monsanto not being able to get patents in their country but then we are exposed to other countries where the patent situation is not strong, and in most cases by virtue of the way they give patents as a product comes off patent, assuming there is no other protection of that product, they will automatically make it if the market of suitable proportions exists.

Q. I just asked you a question about the problems that might occur because of the absence or the insufficiency of patent protection and you gave me your opinions as to what some of the problems might be. What I would like to know is what specific problems has Monsanto encountered in the agricultural chemicals market, pesticide market, as a result of what Monsanto feels is insufficient foreign patent protection?

A. Well, of the three specific cases that I have mentioned, the Hungarians have made one of our proprietary inventions.

Q. Which invention is that?

[34] A. Roundup, which is perhaps the newest and one of the more exciting inventions in the ag-chemical field. The Taiwanese have made two of our products, one being Lasso, which is a herbicide for corn and soybeans and the other beans, and Machete which is a rice herbicide. And in the case of Israel, an Israeli company is making Lasso even though we still have pending a patent application which is going through the prolonged opposition procedures. Actually in the case of Hungary, there are two companies making Roundup. In the case of Taiwan, at one time there were, I believe, four or five companies making Lasso and Machete.

Q. And all of these chemicals, Roundup, Lasso, and Machete, were all patented in the United States at the time?

A. Yes.

Q. Now, the companies in Hungary that were manufacturing Roundup, were they selling that Roundup in competition with Monsanto in other countries?

A. Yes.

* * * * *

[41] Q. Okay. I have got a list—off the track here. I wanted to ask you that a little later but we got to it ahead of time.

Okay. I think we were up to the factor of patentability and proprietary protection as one of the factors which you consider regarding development. Are there any other factors other than patentability and the others that we discussed already which you would consider in developing an agricultural chemical?

A. We talked about the uniqueness of the invention in terms of its application to solve a problem that has not been solved from Monsanto's standpoint. We talked about patents and I mentioned the data protection. Those would be primary issues.

Obviously we would look at what is the likelihood of success, do we have a lead that indicates to us that we can arrive at an invention and obviously as we get further along in the invention process, we will think about the environmental characteristics and work that over very carefully to make sure that this is going to be a compound that is acceptable in the environment that can meet pollution control standards and things of that sort and that there is no adverse effect, per se, that the toxicology is [42] proper, residue, metabolism, and environmental fate.

Q. Are those the major factors, then?

A. I would say so.

* * * * *

[57] Q. How many years now has it been that the Agricultural Chemicals Company has been the major source of operating income for Monsanto?

[58] A. I would say that it's been since the mid-seventies early to mid-seventies.

Q. And what are the projections for the Agricultural Chemicals Company to remain as the leading contributor, shall we say, to the operating income?

A. Well, we're investing a lot of money in research and so we obviously think that research should pay off so we think that the Ag-Products Company should continue to grow if we can continue to develop the technology that is appropriate.

Q. Okay. Do you know when Roundup was patented, the active ingredient in Roundup?

A. I'm thinking. I believe that it was 1974.

Q. Okay. How about Lasso, do you know when that was patented?

A. I'll tell you approximately. Okay? I think that it was in approximately 1969, 1970.

Q. Now, those two of the three—let's get back to your affidavit. You said in your affidavit later on in paragraph three that of the ten major herbicides developed by industry over the last thirty years Monsanto, has developed

three of them. Which would be the three that you would characterize as three of the major herbicides?

A. Avadex, Lasso, and Roundup.

Q. Do you know when Avadex was patented?

[59] A. Again, I'm going to tell you approximately. I think that it was about 1967.

Q. Okay. So then Avadex, Roundup, and Lasso were still under patent, is that right?

A. Yes, in the United States.

Q. Do you know when they expire in the United States?

A. Yes.

Q. Okay. When will Avadex expire, approximately?

A. Let me see. First of all, not to over do this with you, there are different kinds of patents, as you know. There is a compound per se patent on the chemical itself, there are composition patents that involve the compound plus adjuvants, there are process patents, and there are use patents. So when you talk about patent expiration, you know, these patents generally expire in different times but——

Q. Generally do you have each of these types of patents on Avadex, Roundup, and Lasso?

A. It varies from product to product.

Q. Do you have for each product a compound patent?

A. We have a compound patent on Avadex and on Lasso. We have a compound patent pending on Roundup but we have use process—use and process patents.

Q. On each, on all three of them?

A. Yes.

[60] Q. What about on the active ingredient itself? The compound, I would assume, would be the chemical itself or would it be the chemical in its formulated use and process?

A. No, it's the chemical itself.

Q. And that's still pending for Roundup?

A. Yes.

Q. All right. Well, then, when would the Avadex patents expire, roughly?

A. Roughly 1984.

Q. And what about the Lasso patents?

A. 1986, '87.

Q. And what about the Roundup patents?

A. 1991.

Q. Now, it also says in your affidavit in the second sentence in paragraph three that this enormous increase in sales and operating income has been almost entirely attributable to the continual development by Monsanto of new agricultural herbicides. Does that mean that basically the principal operating income which you derived from Monsanto from your Agricultural Products Company in 1980 came from the sale of herbicides?

A. Yes.

Q. Approximately how much of it comes from the sale of herbicides as opposed to the other things that you sell?

A. I would say ninety percent, approximately.

* * * * *

[73] Q. How will that, this 3(C)(1)(D) data consideration or data use, have a substantial impact on Monsanto's sales and profits and a chilling effect on Monsanto's incentive to research and develop new products?

A. Well, it goes back to what I call the proprietary nature of the products. We spend a lot of money in inventing these products and, as you know, it's a very high risk research. For every ten thousand compounds that our industry typically synthesizes, they commercialize one, assuming that EPA is registering products at all, which wasn't the case for a while as you know back in the seventies, and we may typically have twenty to twenty-five million dollars invested in that product before we ever build a plant just to go through the registration procedures, the original research and registration procedures, so it's a very high risk and as I pointed out, of some ten herbicides, we have been fortunate enough to have three of them and I think very clearly while patent protection is one issue, the issue of data protection is also of great importance and if we felt that we could not pro-

tect our data either in terms of [74] it's exclusive use or in terms or data exposure, that would be a very serious deterrent in terms of our wanting to take the same risks. Another facet of that is that, as I mentioned, there are countries in the world where you can't get patents or where the patent system is weak.

Q. I want to limit it to the United States now and data use in the United States. We will get to the second part, the Foreign Countries, in a moment. I'm sorry to interrupt you.

Is there any other way in which you think data consideration or data use would have a substantial impact on Monsanto's sales and profits and a chilling effect on Monsanto's incentive to research and develop new products?

A. You like those terms.

Q. Yes, they're yours. I think I will use them.

A. Yes. If you look at the patentability of products, very often as people synthesize new chemicals, they file product patents that generically cover a number of compounds and it is not at all unusual or unlikely that there may be compounds within that filing that have not precisely been identified as having been superior activity or utility until later in the patent life. And that being the case—or let me give you the second case and then give you the conclusion as I would look at it.

There are also cases where perhaps a person cannot get [75] a patent on something because of obviousness, someone else has a patent and the Patent Office determines that the patent was obvious and you don't get protection in either of those cases and there are a number of those I think that without data protection either in terms of exclusive use or limitations on the data exposure, I think there would be a real question as to whether a company would proceed toward the commercialization of products in that kind of situation.

Q. Okay.

A. Because invariably they are going to have to spend this twenty to twenty-five million dollars before they

build a plant and I just think that they would look at it and say that that investment is questionable.

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TRIAL TRANSCRIPT

PLAINTIFF'S CASE

[41] Dr. Will D. Carpenter, was called as a witness, and being first duly sworn to tell the truth, the whole truth and nothing but the truth, testified as follows:

DIRECT EXAMINATION

By Mr. HEINEMAN:

Q. Would you state your name for the court, please?

A. Will Carpenter.

Q. And where do you live, Mr. Carpenter?

A. I live in Ballwin, Missouri.

Q. And could you tell us by whom you are employed?

A. I'm employed by Monsanto.

Q. And in what capacity are you employed?

A. I am director of environmental management.

Q. And when did you assume that position, Dr. Carpenter?

A. In November of 1980.

Q. And prior to that date, sir, in what capacity were you employed by Monsanto Company?

A. Prior to that date, from 1977 until that date, I was director of environmental operations for the Monsanto Agricultural Products Company.

Q. Now I'm going to get into a little more detail concerning your background, but I'd like you to tell us, a [42] little bit, if you would, about the Monsanto Company. Now can you tell us what is the business of Monsanto Company?

A. Well, basically, Monsanto is in the business of primarily making synthetic fibers and chemicals. We are divided into five operating companies that operate more or less independently: The agricultural company, which I've just mentioned and of which I was a part; the textiles company; the industrial chemicals company, and that covers a whole range of products including aspirin and

plasticizers and flavors and medicines, and what have you; the chemical intermediates company which do just that, provide chemicals that are used primarily to make other finished chemicals; and finally the plastics company which makes plastics; and the various supporting staff units for that.

Q. Okay. Sir, if you would please examine—and let me hand you for your examination what's been marked as plaintiff's exhibit number 1. And I'd ask you to examine that and identify it for us, please?

A. It is a brief summary of the activities of Monsanto, their sales by product, what some of their goals are, where their plants are located, how their organization is made up, how many people work for it, a little bit about the product in each one of those five operating companies.

Q. Does it in general terms talk about where locations of facilities are located?

[43] A. Yes.

Q. Where does Monsanto Company operate, sir?

A. Well, it operates on a worldwide basis, in either sales office or manufacturing, probably in over eighty countries. I don't know whether the specific number is listed there, but it's a broad-based company.

Q. Now let me deal, if I may directly, with the Monsanto Ag Product Company, one of the five operating companies of Monsanto. And you say were a part of that company; for how long, sir?

A. From the time of its formation in 1960 until the time I left in 1980.

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Q. (By Mr. HEINEMAN) Very much so, Judge. Approximately how many employees does the Ag Products Company have, [44] sir.

A. I believe we have around six or seven thousand, in that range.

Q. As opposed to how many employees in the entire company?

A. I think the entire company, in 1980, had about forty thousand, forty-five thousand in the U.S., and about seventeen thousand internationally.

Q. And insofar as the sales of the entire Monsanto Company are concerned, do you know approximately what percentage of those sales are accounted for by the Monsanto Agricultural Products Company?

A. Around sixteen percent.

Q. And insofar as the operating income of the profitable units of Monsanto Company, how much of that operating income approximately is accounted for by the operations of Monsanto Agricultural Products Company?

A. I think it's around seventy to eighty percent; a substantial amount of it.

Q. And to what is that substantial percentage of the operating income of Monsanto Company attributable?

A. That is due to the sales and the profits thereof, primarily, of our herbicides.

Q. And which herbicides do you have specific reference to?

[45] A. The two most important ones are Roundup and another product called Lasso, and then there is several others including Avadex BW, Avadex, Ramrod, Randox. And those are the principal ones.

Mr. HEINEMAN: If the court please, as we go along I have extra copies of these exhibits that he identifies for the court to examine as we go. And copies have been provided to the attorneys for the Government.

The COURT: All right.

By Mr. HEINEMAN:

Q. Dr. Carpenter, let me hand you what has been marked for identification purposes as plaintiff's exhibit number 3, and ask you to examine that and tell the court what it is, please?

A. This is an organizational chart of the technical efforts of the Monsanto Agricultural Products Company, which consists primarily of the development department and of the research department. It gives the various slots,

the titles, and the name of the person that is currently occupying that position.

Q. And I note that pages 1 and 2 relate to the product development group. Could you tell us—now these are all employees of the Monsanto Agricultural Products Company; is that correct?

A. That is correct.

Q. And would you tell us what is the function, generally, of the product development group?

[46] A. Well, after our research department has identified a potential candidate for commercialization; in other words, this looks promising—after a year or two of testing, the product development department then works with the various universities and experiment stations around the country, around the world, in putting out experiments, testing with farmers to see if the product can be used safely. They then further take that test data, and that data is used to submit to the EPA and the other appropriate agencies for their inspection and determination as to the validity of our claims for the product. Then they further, once we have obtained that registration, then these technical people take that expertise and see that our marketing people properly know how to use it, and the customers, and they hold farmer meetings on the proper use of it. So they both generate the data and then they see to it that it's used properly.

Q. Now I note that on page three of exhibit number three, could you tell us in very general terms what that page demonstrates?

A. Well, this is the general overview of the research department. And this gives you in broad terms the various types of research that goes on in the research department. For instance, we have one man that is involved in the various chemicals, another one involved in biological research. The one, moving over to the right hand, is involved in [47] environmental science. And then finally we have one that coordinates our international research.

And this then briefly tells the people that are managing our agricultural research.

Q. Now this research division is only with respect to the Ag products company; is that correct?

A. That's correct.

Q. This isn't—has nothing to do with all the rest of the research department that is out there at Monsanto?

A. Independent of anything else.

Q. Now, if you go to the next page it shows biological research. Now could you tell the court generally what is involved for Monsanto Company in terms of the biological research, in general terms?

A. Well first, we must identify what is an appropriate target for us to go look for. And let's say we are looking for Johnson grass. The chemists will synthesize a chemical and say we think you ought to try this to see if it will kill Johnson grass. The biological group will then devise means of testing that chemical against Johnson grass so that we can very quickly determine if there is activity. For those compounds that look promising we carry out much more involved detailed tests that will ultimately—in each case we're trying to make a decision as to whether to continue with the product or drop it.

[48] And in the biological group primarily they are broken up into two main groups, herbicides or weed killers, and then more sophisticated newer type compounds called plant growth regulators that will cause the plant to do something you want it to do. For instance, one of them we have when applied to sugar cane will cause us to get as much as a ton of sugar more per acre off of sugar cane. It fools the sugar plant into producing more sugar, if you will. So this is the biological group.

Q. Now these plant growth regulators of course are governed by and regulated by the environmental protection agency?

A. The same laws, same regulations that govern pesticides.

Q. And their safety has to be determined by that agency just as you would a weed killer.

A. Exactly the same.

Q. Now if you turned to environmental science, sir, which is on the next page. I note that is under Dr. Sharp. Could you tell us what—generally what that department does?

A. As a compound shows promise for commercialization, among those things we must find out as soon as possible and continuing through its commercialization, its impact on the environment. Now in order to do this we must determine what happens to it in the soil, what happens to it in the water, [49] what happens to it in animals, what happens to it in crops. We need to know how much is there, in what form is it. And all these are studied. In addition to that, what happens if quail are sprayed, what happens if rabbits are sprayed, the impact on wildlife, on fish and in lakes, and so forth. So this group carries out those studies that determine the impact of the chemical on the environment.

Q. And those results—those studies again comprise data which is submitted to the Environmental Protection Agency?

A. Yes, it does.

Q. Now the next page shows the organization of the synthesis department with Dr. Rueppel in charge. Could you tell us what that group does in general terms?

A. Well, these are the people that synthesize or make, invent, discover new chemicals. By and large we find that these people, in order for us to get up to what we call critical mass, get enough there that we've got some odds at discovering, we need to invent, discover somewhere between five and ten thousand new chemicals a year, because we're only commercializing about one out of ten to one out of twenty thousand chemicals.

Q. Excuse me, when you say one out of ten you mean one out of ten thousand?

A. One out of ten thousand to one out of twenty [50] thousand chemicals eventually reach commercialization. so that these people are charged with several things. First of all they must be smart enough to figure out what are new techniques of making chemicals, and then what can be done with old areas of chemistry to modify them so that you then have new chemistry.

So just the making of chemicals is not as important as figuring out how to go make something—a completely new class of chemicals, and developing new techniques for making them. And this is a part of the synthesis group.

Q. All right. Now I will get into more detail on that synthesis effort later on. But I just want to have a general flavor of what these various groups do.

Next we show chemical research. What do they do? Does that differ from the synthesis group?

A. Once we have made a chemical and decided that it is indeed worthy of commercialization, then we must have people that must go do several things. One is how to make it in a million pound plant as opposed to a few grams in a test tube. And that's the process group. Then in addition, having made the chemical we must put it in a form that the farmers can use effectively. The chemical as it is, by and large, could not be used by the farmers, but must be put in such a way that the farmer can put it in his fertilizer solution or in his water, or mix it with his seed or [51] whatever, and do it effectively and safely. And that is the formulation group.

Q. And that's on the next page we see process/formulation technology?

A. And that is merely an expansion showing the detail of what—of the two things I have just described.

Q. And these are the people that actually do that work?

A. That's correct.

Q. Now where are these people located? You mentioned some—you mentioned something about an international department. Where are the people located?

A. Well, a great number of them are at research labs here in St. Louis. But in addition, we have research facilities in Brazil, in Europe, in Latin America; in Asia we conduct—also conduct research and development. So in a word we have been worldwide.

Q. Now I note on page nine we have plant sciences. Can you tell us what that group accomplishes?

A. Well, in addition to looking for the conventional chemicals that will control an insect, control a weed, control a fungus, we have substantial commitment to looking at new ways of controlling insects and diseases rather than just using chemicals. For instance, we found that we can actually cause the plants to make their own antibodies, [52] if you will, to make it the pop expression, whereby the plant will secrete the chemicals that will kill the pest rather than having to use a chemical to do it. In other words, we make a plant resistant to an insect or to a fungus, or we could spray it so that the weeds don't bother it. And this is what things like the disease insect control group, host/patogen group, and the cell biology group are doing. They're actually maybe even trying to invent new plants by isolating special cells of the plants and culturing new plants that will be resistant to herbicides. For instance, you could spray them over the top without having to worry about crop damage. So this is the far out group. This is the group that are looking for things that will be our product after the year two thousand.

Q. When you say develop a plant that would be resistant to herbicides so that you could spray right over the grown plants, would you develop that a little bit? What are you talking about there?

A. Well, no herbicide is perfect. We'd like to think that we've come close a few times. But no herbicide is perfect, there's always a way to damage a crop plant, damage your soy bean crop if you put on too much, or damage the corn plant if you get it in the wrong place. Well, if we could treat the corn plant so that no matter how much of

the herbicide you got in the wrong place, or sprayed at the wrong time, [53] it would not damage the corn plant at all whether you sprayed it when you planted it or sprayed it over the top. The corn plant would then become resistant, so that then you could get the weeds any way you wanted to.

Q. What benefit would that have to the farmer and to yields?

A. Well first of all, it would give him access to a wider range of herbicides that he doesn't have a choice of. It would take off the impact of just about the time he gets ready to spread his herbicide it rains and he can't get back in the field for two weeks. And by then either the crop is at a stage where it will be damaged, or the weeds are too big to be killed. Well, if you have one——

The COURT: Off the record.

(Discussion off the record.)

The COURT: Go ahead.

A. But at any rate, this is getting into materials—all of these techniques, I imagine, would be a substantial improvement in the environment. You're then dealing with products that are not biocides, but chemicals that stimulate certain parts of life. So that you would get an improved impact on the environment that way.

By Mr. HEINEMAN:

Q. All right. Next I'd like to have you identify what's been marked for identification [54] purposes as plaintiff's exhibit number 2. I have a more manageable version for the court.

Now Dr. Carpenter, if you would please tell us what plaintiff's exhibit number 2 is.

A. This is a map showing the location of all the various facilities of the agricultural products company's operations. The red dots being our marketing and our development groups and the triangles being——

Q. Which are blue?

A. Blue—our research facilities. And our manufacturing locations being square black, I believe, or green; green

perhaps. We keep our marketing and our development and our technical people together so that we see that our technology is used properly. Our manufacturing facilities are, for the most part, concentrated in the U.S. But we still have manufacturing facilities in a large number of countries: Canada, Brazil, Argentina, Europe, Australia, Korea. And they're quite widespread, and by and large, in the key agriculture countries of the world.

Q. Now you mentioned, sir, something about keeping facilities together in certain locations. Could you elaborate on that a little bit?

A. Well, if we identify a new agricultural opportunity, let's say in South Africa where they grow a lot of corn, when we go down there and test this, by and large we're [55] doing two things at once. We're trying to establish a marketing system, what distributors do we use down there, how does the farmer buy his material, or how does he pay for it, how his material is warehoused. But at the same time we have a rather extensive technical program too, and those two programs have to go together not only initially but down the road. A product that works well on corn in Missouri may or may not work well in South Africa. And you have to carry out the same type of intensive testing in South Africa that you do in Missouri. Or if it's wheat, you carry out a very intensive program in Australia just like you would in North Dakota. So that we keep our technical and our marketing people together so that the technology is transferred correctly.

Q. Now you also mentioned something about test farms. Would you tell the Court generally what you mean by that expression.

A. Well, we have farms just as the University of Missouri or Illinois has, where they have their experiment station farms. We have them also whereby we can control experiments over several years that we want to follow the fate of a chemical in the soil, where it can be on our own land and under our control, where we can carry out very elaborate experiments. And this farm is set up to

conduct very sophisticated experimental procedures very similar [56] to that done at the agricultural experiment stations that are a completely different type, nature than done there.

Q. In what respect is it different?

A. Well, the agricultural experiment station is usually set up to solve a problem for the farmers in Missouri. Usually this is limited to the study of new varieties or control of certain pests, or crop safety. Ours are to test a wide range of chemicals, probably on a given crop, that may or may not be a major problem. For instance, we will test all crops at our farm here in Missouri on crops that are—weeds that are important in Belgium because we want to get as much information as soon as possible. We'll test it on weeds that are problems in Canada, like quack grass. Quack grass in Canada is as big a problem as Johnson grass is in Missouri. We will also carry out various types of experimental design equipment, like means of controlling photosynthesis whereas you have the same types of scientists, their skills and experience and types of experiments would be different than those at the University of Missouri or in Illinois.

Q. Dr. Carpenter, I wanted to get you started initially talking about the company itself, and would like at this time to have you tell the Court something about your personal background. I know that you received a bachelors degree from Missisippi State. Can you tell the Court in [57] what year?

A. I received my bachelors in 1952 in agronomy, soil chemistry.

Q. And for the benefit of the record, sir, would you tell us generally what agronomy is?

A. Agronomy is the study of crops—usually, most ecologists—crops and soils, and specifically what we call field crops such as cotton, corn, soy beans, rice, as opposed to horticulture crops, which would be your various fruits and vegetables.

Q. And after graduation from Mississippi State what did you do then?

A. Worked briefly at an experiment station in Mississippi. Then I went into the service and was in the artillery in the U.S. and Korea, and was there until mid to late 54, 1954.

Q. And what did you do then, sir?

A. I then went to graduate school, to Purdue, got a masters in 56 and a Ph. D in 58 in plant physiology.

Q. All right. Now would you tell, for the record, what plant physiology is, basically?

A. Plant physiology is—represents a study of the functions of the plant, how does it make certain things happen, how does it get its energy to build new cells, how does it trap the light from the sun for photosynthesis, how does [58] it transport things from one part of the plant to another, this type of thing, functions within a plant.

Q. Then in 1958 you joined Monsanto Company?

A. That's correct.

Q. In what capacity, sir?

A. I joined as a research chemist in plant and animal nutrition studies. And then went to some rather basic biochemical studies, synthesizing radioactive materials for studies on cell wall synthesis. And then in 1961 joined the Development Department of the Agricultural Company.

Q. And what generally did you do in the Development Department?

A. Well, we worked very closely with the universities and experiment stations. At that point in time I was working in the southeast quandrant of the U.S. I had about twenty States ranging from North Carolina across through to Missouri, Arkansas, and Texas. And we would work with the various scientists at the university. If they would have an objective of solving a problem say in Missouri, I would have a chemical that I thought was a condidate to solve that problem—now I wanted to solve it in Missouri and North Carolina both, they didn't really care

whether the solution came from Monsanto or Dupont or whoever. But both of us were interested in trying to control that patricular pest, so to that extent our objectives overlapped for a fair amount, [59] and so I would conduct my own test, put out my own experiments and visit with experiment stations, review their results and look at their tests, and then relate this back to what we should be doing with our product.

Q. And you served in that capacity for four years, until 1965, when you became manager of herbicide development; is that correct?

A. That's correct.

Q. And did you then continue generally in the same type of functions?

A. Yes, except at that point in time my responsibility became worldwide, and I spent a great deal of time traveling to a number of other countries seeing to it that we were then doing what I had been doing in the U.S., that we were setting up procedures and hiring people to look at agricultural problems on a worldwide basis in a manner that we had been doing it in the U.S.

Q. And you did that until 1968. And what—how did your functions change then, sir?

A. Well, I then became director and we then enlarged our operations considerably both U.S. and—domestic, and put a number of scientists across the country carrying out, with our own forms and so forth, these experiments on a much more intensive scale.

Q. And then in 1977 I think you previously testified [60] you became Director of Environmental Operations for the Agricultural Products Company?

A. That's correct.

Q. Now in these capacities with Monsanto Agricultural Products Company over the years have you had any connection with the registration functions?

A. Yes.

Q. Would you please tell the Court?

A. Well, in the early days, in 1961, the registration functions was a matter of the Development Department. And a number of us prepared a petition to submit to U.S.D.A. at that time. In 1968 the registration functions as such moved over to research, and organizational change, but we still generated the use data and did the residue studies on locations that were a part of our registration procedure and were submitted. And that arrangement stayed until 1978 whereby we participated in writing the label, drafting the proposed label to be submitted to EPA, plus the efficacy data on how effective it was, crop safety and the residue locations. Then in 1978 after I had become Director of Environmental Operations, the registration group was transferred over to me and reported to me. So that the registration group, those that prepared all of the data, pulled it together, our Washington representatives and so forth, were a part of my group.

[61] Q. Now during the time that you were in the product development functions, was that the time when lasso and roundup were discovered?

A. Yes.

Q. And then were you then responsible for the development effort on those two products?

A. Yes, I was.

Q. Now in these various functions that you have served in the Agricultural Products Company, have you had occasion to become familiar with the cost and investment in research and development by the Ag Products Company?

A. Yes, yes. This has been a part of my responsibilities since 1961.

Q. And what connection, if any, have you had in those capacities with patent applications and product registrations and the data submitted for each?

A. Considerable. Patent applications are usually a direct relationship between the synthesis chemist and sometimes the biologist and the patent attorney. But the value of the impact those patents have, determine to a large extent what chemicals we test. So that the relation-

ship between development, the patent attorney who's handling our patents, and the Research Department is kind of a three-legged stool. And the interchange between the three must go on at all times. The data as opposed to patent data, [62] which is a very narrow small segment of the data that is used for registrations, is probably a couple of orders magnitude greater in complexity, amount, time to get it and so forth. And there we work towards—I worked and had responsibility for seeing that the registration data was given.

Q. All right, sir. I'd like to hand you what has been marked for identification purposes as plaintiff's Exhibit number 8, and ask that you examine that and identify it for us, please.

A. This is a biographical sketch of my activities primarily since I've joined Monsanto.

Q. And I note in connection with that exhibit there is some discussion of some trade and professional societies. Would you tell us what these regional weed science societies are that you belong to?

A. Okay. The North Central Weeds Control Conference comprises the professionals from Michigan and Ohio and Kentucky across through the Plain States, Nebraska, Kansas, North and South Dakota and Oklahoma. It's a professional society of something less than a thousand members from the universities, from the Government, and from industry. And their common bonds are those scientific aspects of weed control. I served as president of that in the mid-70's.

Then we have a national organization that is independent of the regional ones which comprise the professional [63] scientists of both Canada and the U.S.—and I was president of that organization in 1980—of about two thousand to twenty five hundred members.

Mr. HEINEMAN: Now, your Honor, we would offer, Exhibits 1, 2, 3, and 8 at this time.

The COURT: Is there objection?

Ms. MAYER: No objection.

The COURT: It'll be received. Off the record.

* * * * *

By Mr. HEINEMAN:

Q. Now Dr. Carpenter in connection with the scope of FIFRA, can you define for us that a pesticide is?

A. Well, a pesticide is any substance——

Ms. MAYER: Your Honor, objection, as far as he's asking the witness to testify as to the legal definition of FIFRA.

The COURT: Well, overruled. Go ahead.

A. A pesticide is any substance that is used to control, kill, mitigate, reduce a pest. And pesticides include [64] the categories rodenticides, which is mentioned in the act itself; fungicides and insecticides. But it also includes herbicides and plant growth regulators, so it's a fairly broad category that comes under the definition of pesticides. Any time the substance claims are made for controlling pests, it comes under the purview of that.

By Mr. HEINEMAN:

Q. Of the act of FIFRA?

A. Yes.

Q. So that a plant that may be very desirable in one context and undesirable in another, would be a pest in the other context?

A. Yes. The example that always gets everybody's attention is a rose in a cornfield is a weed.

The COURT: Well, Johnson grass makes pretty good hay if you cut it before it heads up.

A. But if it's in your soybeans that's something else.

By Mr. HEINEMAN:

Q. All right. Let me get into a brief historical overview of pesticides and how they have been developed over the years. Before pesticides came along what did farmers do to control weeds?

A. Well, over the years as far as controlling weeds there were two things they did. They had human labor, which was the first thing. And that means pulling them out by hand or use of a hoe. And that still represents the single [65] biggest source of human labor in the world

today, is taking weeds out of crops in most of the world. And then animal labor, which is nothing more than the mule and the double shovel, or running cultivators and so forth. And then ultimately mechanical energy, if you will, and that's the use of tractors and still just more sophisticated cultivation instruments. So human, animal, and mechanical labor was used to remove weeds.

Q. Okay. Now prior to World War II, I, guess, is when the first pesticide came along in the herbicide arena; is that correct?

A. That 's correct.

Q. And could you tell the Court what those were?

A. Well, just prior to World War II they had very simple inorganic compounds that you commented on earlier, such as sodium chlorates and even things like the arsenic compounds which were inorganic, and they were used. But they were non-selective. In other words, they would not allow plants—crop plants to grow either. It wasn't until after World War II that we got into the so-called organic selective herbicides.

Q. Now in the early days of these herbicides were any of these materials proprietary?

A. The first proprietary herbicide that was on the market, to my knowledge, was Dow came out with a product [66] about in 1950, thereabouts, called premerge. The products previous to that were primarily known as the phenoxy group which is the 2,4-D, 2,4,5-T group. And those were more or less came out of the Government screening during World War II. And those were not proprietary.

Q. Was there a term that you would use to describe those compounds prior to the proprietary ones coming along?

A. Well, in terms of the type of weeds they were used on, that would be one way. In terms of how they were located on the marketplace you could call them commodity chemicals, indicating that they were widely available from different sources like fertilizers or like seeds. You

could go buy soybean seeds from different people. You could buy fertilizers. Well, there were a large number of manufacturers of the phenoxy 2,4-D's and 2,4,5-T's.

Q. Did Monsanto manufacture some of those products?

A. 2,4-D and 2,4,5-T and some of the others.

Q. And there were other companies as well that did the same thing?

A. At one time there were up to ten to fifteen companies that manufactured those particular products.

Q. And those you say arose out of World War II?

A. The phenoxies came out of World War II research, yes.

Q. Now how do you differentiate that kind of a [67] chemical from what you called a proprietary chemical?

A. Well, in my mind a proprietary chemical is one that comes out of a company's research program where it identifies a chemical where nobody has identified it before as being a herbicide, and conducts the research that leads to commercialization as a herbicide, and at least initially is the only supplier of that herbicide. It's their proprietary knowledge that led them to it. Whereas a commodity chemical comes out of some large public body of knowledge, commodity chemical does.

Q. And what were the best known post-World War II commodity chemicals?

A. Well, in the field of herbicides it was 2,4-D and 2,4,5-T by far. There were a number of insecticides that were used. I am more or less in the area of herbicides, and I'm not too familiar. But 2,4-D and 2,4,5-T were commonly regarded as proprietary. Parathion and methyl parathion which were used for insect control on cotton and other crops came out of World War II in a slightly different way in that they were identified in part through the German poison gas program during World War II. And there were several manufacturers from the beginning, of the parathions.

Q. Is DDT a chemical of that type?

A. DDT is another one, yes.

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Q. Now was the efforts, as these chemicals developed, [68] to make them selective as opposed to wiping out the crop along with the weed.

A. Well, these compounds were the beginners of that, of a group of pesticides that could be applied selectively. In other words, they could be put on—the phenoxies could be put on corn without killing the corn. And they would kill the broad-leaf weeds. That was the definition of selective. And yes, the D's and T's were selective.

Q. Now I'd like to discuss somewhat with you, or have you describe to the Court, the correlation, if any there be, between the growth and U.S. agricultural product activities and the development and use of pesticides, and in particular, if you could discuss that in the herbicide arena, please?

A. All right. Well, if you start all the way back to when man started agriculture, probably the first thing he did was his own selection of seed rather than just depending on growing plants from the wild. So he selected and saved his seed and then learned to cultivate. And then he learned eventually to apply fertilizers. And then he eventually learned how to apply other components. He tried to control his pests. And the first thing he tried to control were the insects and the diseases. These were the most obvious. Being able to control weeds was about the last thing he was able to do other than by the use of labor. And [69] gradually as he got to where he could use herbicides he had brought in a number of minor scientific agriculture. So yields had already started to increase. So we had hybrid seeds and good fertilizers and we recognized how to take care of the land.

Then beginning at that point, in the late 40's, things that were really limiting production at that time, perhaps as much as anything, was the ability to control the weeds that competed for the plant nutrients, for the moisture, sunlight, and what have you. Soybeans is a particularly good example since they're grown in a large part of the country. You can pretty well plot the soybean yield per

acre, annual average yield per acre, starting in about the late 50's, early 60's until now. And there was a very close parallel with the better soybean herbicide that came out and the yield of soybeans. You just couldn't grow soybeans in certain parts of the South and the Midwest, and some of the heavy soil areas because of Johnson grass, crab grass, what have you. And many fields would be abandoned. And being able to get twenty bushels per acre or thirty bushels per acre rather than zero, just done wonders to the soybeans yields per acre.

Q. And what is the largest cash crop in the United States today?

A. The largest cash crop, depending upon price, is now somewhere between wheat and soybeans, displacing—[70] cotton use to be way up there. And now wheat, corn, soybeans are all extremely high, and the acreage has continued to increase.

Q. How many acres a year are planted in the United States in terms of soybeans and corn production?

A. Corn is now approaching between eighty and ninety million. Soybeans are now approaching between sixty and seventy. In the late 50's, early 60's, soybeans were less than half that and corn was actually about a little bit less than that. But the soybean acreage has almost doubled in the last thirty years.

Q. Does Monsanto anticipate any connection between the yield in terms of soybeans and corn production, and the use of plant growth regulators?

A. Yes. We think that the future of plant growth regulators, these materials that can modify the growth of plants, will do as much for agriculture as the use of pesticides have done in the last forty years. We think that they can represent the next big growth opportunity for increasing agriculture yields.

Q. Let me get a bit, if I may, into the subject of the research and development of a pesticide. Now can you tell us what all the considerations that—well first of all, let me step back a moment and say now in your capacity

with the Monsanto Agricultural Products Company did you have any [71] participation in the decisions about the development of pesticides?

A. Yes.

Q. And was there a group that you participated in in which you made those decisions?

A. Yes. We used various terms for the management group, and the composition changed. The term that we're now using, and used from about 1973 on, was called the new product board. In the mid-1960's we used the term pesticide product board. And those terms have shifted. But yes, there is a management board. I was on the pesticide product board in the 60's, and then I joined the new product committee board in 1976.

Q. And in terms of the decisions and considerations that go into developing a pesticide, can you tell us what the problems are that you take into consideration?

A. Well first of all, the company has got to decide whether it really wants to get into the pesticide business. It's got so many dollars that it can afford to spend on research or development. And it's looking at a lot of competing places to spend that money. It can spend it to go find a better aspirin or to find a better plastic, or to find a better soap, or to find pesticides.

So when they name a commitment to get into the pesticide business they have got to make a commitment to get into [72] the business with no pay back. They better plan on no pay back for anywhere from ten to twenty years.

Now the thing that you have to take into consideration when you want to get into the pesticide business is this. First of all, I want to find something to be solved that's a big problem out there. It's got to be awfully big because if it's going to take you a long time to find the solution. When you find it, it better be a pretty big solution. Another thing is, it's got to be a very difficult problem to solve, as only those organizations that are willing to commit to a long-term effort and apply a lot of resources to it are going to be the ones that have a chance at solv-

ing the problem. So that there aren't going to be that many people out there trying to solve it in the first place.

And then finally, it's got to be a problem that will still be a problem twenty years from now, because it could take you that long to solve the problem. And if you look at it and say I'm going to solve that problem now, and it doesn't exist twenty years from now, then you've got a solution with no place to go.

And then finally, it's got to be a problem that you think you can find the solution, that you can provide it to the farmer, that he can use it effectively and safely and make a profit by using it, and at the same time you can sell it to the farmer and you make a profit.

[73] Q. What about the economic investment that is involved in a thing like that?

A. Oh, the economic investment is substantial. In the first place, you have to put together a highly trained complex scientific team. We think that the scientific team should have somewhere at a minimum of a hundred and fifty to up to five hundred or more scientists in order to be effective. It takes you a certain number of years just to assemble and get this scientific team functioning. It takes you a certain number of—oh, a couple of years or better to just identify the key targets that you must search for. You've got to get facilities and equipment for them. You've got to generate a procedure so that—and if you find a compound, from the time you find the compound it's going to take you so many years. And it might take you anywhere from one to ten years or longer to find a compound which you can then start commercialization.

So by the time you actually are able to sell your first pound, forgetting about building the plant or the cost of materials, you have got a substantial investment. So you've got to make a commitment to the long-term. And most pesticide companies that got into the business by virtue of this were not profitable the first several years that they were in business.

Q. What sort of anticipated return on investment do [74] you have in terms of the target that you look for to solve?

A. Well, you want an extremely large return on investment for the ones that's successful, because it's not only got to pay for the enormous investment of that particular compound, it's got to pay for the nine thousand nine hundred ninety nine losers. If you're maybe commercializing only one out of ten thousand, you still got to synthesize the losers and go through all of that. That eventually has to be underwritten by the one winner.

Q. And in synthesizing—or I should say in commercializing one out of ten thousand, which I think you said is what Monsanto accomplishes——

A. Yes.

Q. To your knowledge, how does Monsanto rate among the other companies in that sort of success ratio?

A. Several of the companies have used, over the past, a numbering code for their coded compounds somewhat similar to Monsanto's. We number our compounds consecutively. Lasso was CP 50144, fifty thousand one hundred forty four. Roundup had still a much larger number. Based on that—for instance Baker's Sencor was 94337. They had synthesized and screened ninety four thousand three hundred and thirty six compounds for a herbicide before they hit on Sencor. And that was their first. Based on various industry estimates and my estimates, I believe that the industry is hitting on [75] about one out of twenty thousand. We're hitting on about one out of ten, one out of ten thousand.

Q. Now approximately, annually, what does it cost to carry on this R and D program you're talking about?

A. Well, of course the cost depends upon the scope of operations. Back in the 60's our annual research—in the late 50's, early 60's our annual budget for research and development combined was probably in the range of anywhere from three to ten million. And it increased every year. I think our annual research budget for 1981 or 2—I

don't know whether it's this year or last year's, but at any rate, I think its fifty nine million dollars for research, and probably somewhere in the range of ten to twelve million dollars for development. So we're now expending somewhere between let's say sixty and eighty million dollars in the agriculture company for research and development for agricultural chemicals.

Q. What are the reasons for the increases over that period of time?

A. Well, there are a number of increases, inflation obviously. But the complexity of the scientific procedures, the cost of equipment, because of the more extensive methods of analysis of chemicals that has increased by a factor of—since the sensitivity of analysis has increased by a million. So where we use to run it with a piece of equipment that [76] would cost say ten thousand dollars, we now might have three hundred thousand dollars in a piece of equipment to measure a pesticide. That has entered into it. The fact that as new pesticides are brought on the market there are new standards which you now have to beat. When we brought on Lasso we only had to beat the level of excellence that was out there in '65. For the people that now want to beat Lasso they have to bring on a compound that is better or equal to Lasso. So that the competitive standards are higher.

And then superimposed on all of that is the regulatory requirements are far more complex. There are more of them, and they take longer to do and with any given—any given requirement. Whereas we use to do ten yield studies, we might now do forty. Where we use to have to do four residue analysis, we might do eight. And when we do the eight instead of just measuring at the time of harvest we now measure at four weeks after the crop emerges, at eight weeks, at silage, and at harvest. So that it blossoms out to become a far more complex costly timely procedure than it was.

Q. Does the increase in technology with respect to detection levels have anything to do with that?

A. Oh, substantially. This is the point I was making earlier. When we first came out with a compound for corn and soybeans in 1956 called Randox we were very happy because we had a method of sensitivity that was around one or [77] two parts per million, which in turn was better than anything even possible four years, five years before that. The next product we came out with we had to go to tenths of a part per million. Now we're routinely going to hundredths of a part per million. And in many cases we're easily into parts per billion. And when you increase that sensitivity by a thousand to ten thousand to a hundred thousand fold, the cost of equipment to do that increases by a great deal.

* * * * *

[90] Q. (By Mr. HEINEMAN) Dr. Carpenter, let me ask you now if you would discuss the risks that are considered by Monsanto Agricultural Products Company in determining to develop a particular pesticide?

A. Well, the biggest risk represents, as I look at it, [91] a risk of pursuing losers. And if I could pursue that point, as I indicated, one out of ten to twenty thousand—and for the purpose of this you can take either one you choose—you only have that one winner. But you don't know which one it is, so you've got to devise a procedure by which you can identify the losers and wash them out and get them out of the way so that you can then work with the winner.

The COURT: Like an Edsel?

A. Well, hopefully better than an Edsel. We have had our share of Edsels too. But usually what you do is, the end of a year—if you're screening anywhere from three to five to eight thousand compounds a year, usually at the end of the year you've got about ten of those compounds left that you think are pretty good. You're then looking at those ten and you're saying that on one hand that's all I got left that I spent forty million dollars for, in so many words, at thirty or ten or whatever you spent on your research budget. And so to that end you're saying

I'm obligated to see whatever I can do to find those, a winner for those, a place to commercialize those. On the other hand, in all probability there is only one of them that's a winner. And the sooner you make a decision to get rid of those other nine and devote your resources to either looking for the winner that's there or going back and starting over, the better off you'll be.

Now if you say well, I'm going to consider them all [92] winners, you have to start what I term a number of clocks running at the same time because of the time lag. And I can get into this in more detail later. But for instance, without any delays at all to be absolutely as efficient as you can be, it takes you somewhere between forty eight and fifty six months to complete the toxicology studies if you say I'll do nothing, without stopping. If you're going to develop a good process to make this in multi-million pound quantities, from the time you have somebody that knows how to make it in a test tube until you can make it in a plant like down here at Queeny, it's going to take you anywhere from three to six years to develop a process, try it out in a pilot plant, get the capital, build the plant. And the same goes for all these others. If you do all those things consecutively or simultaneously rather than try to do them consecutively, you never get to the end. So you have to start doing all those things at once.

And then the amount of money you start spending to make sure that you're doing all those things at once so you can have commercialization, registration, as soon as possible, the expenses become inordinate and the ability for you to make a proper decision on whether to stop and drop that loser or near miss, and whether to continue on, represents the single biggest risk and probably the single biggest cause of failure of companies, having to get out of the business. [93] They were not able to separate out the near misses from the winners.

And you can lose on any one of those. If the toxicology is not right, regardless of the process you lose. If the toxi-

cology is good and it's going to—the cost is inordinate per pound, you lose. If the production is not consistent year-end and year-out with the farmers, yet you've got good toxicology and it's a cheap product, you lose. So you can lose on any one of those tracks. And you have no choice but keep them all going.

So the ability is to take science, experience, and sales and be able to develop that technique for identifying winners and eliminating losers and doing it in the most effective way possible.

By Mr. HEINEMAN:

Q. Now are some of those techniques involved in developing the data, that is, the data that is submitted to the Environmental Protection Agency?

A. Yes, they are almost inherent in that.

Q. And in the data that is submitted to the Agency in support of a registration, are those techniques set out?

A. A number of them are part of the data submitted to the Agency.

Q. Now the potential marketsize of the product that you're—or the target that you're looking for, is that a risk that is taken into consideration by the company?

[94] A. Yes. If you were wrong on your assessment of the marketplace, whereas, you thought a market was big or growing and in turn it got smaller or disappeared, you could have a technical success and a commercial failure.

Monsanto's Edsel was—we had a product for a crop called safflower back in the late-50's and early-60's. It looked safflower was going to be the coming oil seed crop. It was going to go all across California and the Northwest, and it was going to be a big acreage crop. And we found a product that worked for it, and it worked fairly well. And we got it cleared except that the bottom fell out of the oil seed market. And the safflower acreage, instead of doubling or tripling, went down to about one-fifth of what it was. And we had no available market. The volume dropped off to where our cost per pound quadrupled. And the more we sold the more we lost.

Q. What is the name of that product?

A. Lambas. It took lambs quarter or weed out of safflower, so we called it Lambas. And that was our Edsel.

Q. Now is there some consideration with respect to the availability of raw materials?

A. Yes. Not only do you have to make the chemical itself, but in many cases you've got such a new area of chemistry that even the raw materials or the intermediates are not available in sufficient quantity. In the case of [95] Roundup we require a phosphorus intermediate in large quantities. And the amount that we needed was more than the total world supply of that chemical for all uses. We had to go to another company and persuade them to increase their production capacity so that they could supply us the intermediate so that we could make the material. And that sounds like a fairly easy situation because anybody is glad to have a guaranteed market. But if they're going to bring their plant on stream in time for your registration, they've got to be persuaded to start building that plant three years or more before you ever obtain your registration. So you've got to persuade them to bet the come also, so to speak, because——

The COURT: Anybody here who doesn't understand the last phrase?

A. I'm sorry, your Honor.

The COURT: That's all right, I know what it means. You can bet the field or you can bet against the roller or you can bet on the come, which means you're betting with him normally, except for some crap tables I've seen. And this may be apropos to the situation, but there's an old saying down in the hills where I come from, just before you do I bet you don't. Go ahead.

By Mr. HEINEMAN:

Q. All right. What is the time involved, on the average, in terms of Monsanto's experience, [96] from initial synthesis to full commercialization?

A. We have had approximately ten products that we have registered with EPA as herbicides from 1956

through the present. Obviously as we register those throughout the years the requirements have changed. But in today's, and since the mid-70's on, it's been our experience that from the time we see the product the first time until the time we had our first full registration that accompanied the tolerance, is six to eight years.

Q. When was the last time that Monsanto discovered a new winner?

A. Our last new product was Roundup which was commercialized for non-crop use in '75, and for full crop use for several crops—not for full crops but for several crops, in 1976. So it's been six years.

Q. Are there any changes in the technology in agriculture that can effect the success of a commercialized pesticide?

A. Yes. That has a substantial impact. If crop patterns are shifting, for instance, if they go from full row beans, soybeans planted forty inches apart to narrow row beans or to broadcast or drillbeans that you would do with small grains, those products that were based on treating a portion of the field called ban treatment because of the high price, you reduce the cost by doing that. If all of a [97] sudden soybeans switched to where the only way you can apply the chemical is broadcast it and thereby price it out of the market, then that product will not succeed. So that here's where a technological change, the way they plant soybeans, could have an impact on a product.

As we go to conservation tillage in corn by preserving the soil, keeping the soil runoff, leaving the trash and the plant debris on the surface, there are those chemicals that will work only on a very smooth, well-prepared soil bed where there's no trash or plant litter. If you have a substantial number of acres then that have this trash litter on there, then this product no longer has a viable market on those acres, and that will impact the future of that product.

Q. How about in terms of tillage or cultivation or development of new agricultural equipment?

A. That will have an impact in this conservation tillage. It will take different types of seeders to cut through that trash. And if those seeders are unavailable the concept doesn't work.

So you can lose by changes in equipment, change in weed controls in the weeds that are out there. As the people have gone to less and less cultivations we've gotten different types of weeds that were there when they cultivated a lot. Some of the old chemicals controlled the weeds that were there. Now that we've had a shift in the weeds spectrum [98] these chemicals don't work anymore.

The COURT: What you're saying is the old practice of checking corn is long gone?

A. Yes, sir; yes, sir.

By Mr. HEINEMAN:

Q. So, as I understand your testimony, Doctor, there can be changes in the pests themselves?

A. The pests themselves can change. With insects, of course, resistance is well documented with everybody knowing that DDT doesn't kill the housefly anymore, and so forth. With the plants, with herbicides, it's although resistance has been documented in a one or two cases, the big shift there is changes in weeds. In the Midwest when they were growing corn right after World War II there were broadleaf weeds like pigweed and lambs-quarters and so forth. And the D's and T's did a wonderful job, but as they killed them the grasses came in behind them, the crabgrass, the foxtail, goosegrass and what have you. And the new materials would not—the old materials, the 2,4-D's and 2,4,5-T's wouldn't control them. And they started a downward decline and eventually essentially no longer are a factor in the corn market and then you needed a new material that will control grasses. But when you start looking for the new material you better figure out is that going to be a problem twenty years from now. If you look for it in '52 will there be a grass problem in 1972. [99] Q. All right. What if anything have the changes in the regulatory requirements had to do with the consider-

ations that the new product committee would think about when they were deciding whether to commercialize a pesticide?

A. Well, two things immediately. The first is the time lag. In other words, it's now taking longer to generate the data. And by the large, at least certainly in the period of the late-70's, the period in which the petition was under review by the agency was much longer. So that you got stretched out two ways. The time it took you to get the data and the time it took the agency to review the data.

In terms of expenses, it obviously cost you more to get that data and the risks became higher that you were going to succeed. What that did in turn then was to say, I will use a bigger denominator. In other words, where I might could, at one time, commercialize a product for vegetable crops for tomatoes or carrots or cabbage which are a few hundred acres, you now no longer can commercialize a product for that use. And you now say I'm commercializing one for potatoes with a million acres, or dry beans with a million or so acres. And now you're saying I better have a product that I need that has a ten million acre potential. So you change your commercial target or you change the minimum acceptable commercial target by virtue of the increased cost and the increased risks.

[100] The COURT: Just a minute. Let me ask one question here. Let's talk about Roundup and let's assume that, for whatever reason, the data is disclosed not by you but by EPA or whoever.

A. Yes, sir.

The COURT: From what you testified I gather that the hit or miss proposition is controlled, at least to some regard, by the ability to manufacture and process, etcetera, etcetera?

A. [Nodding head.]

The COURT: Now does the data infer or give to competition any suggestions as you which way to go from the standpoint of raw materials, productivity and things of that nature?

A. That part, the formulation part and the manufacturing process is held confidential under the current laws. That is not to be released. What is——

The COURT: Do they even have it? They have it though, do they not?

A. Yes, they do have it. We submit that routinely as part of our registration procedures. And it is in the file, but that's in the law that it is not to be released. What is in the file though that gives people the lead is the method of analysis, the procedures we use that would allow someone, if they so chose, to take our procedures. [101] And either one, use our techniques as a means of increasing and using that in their own research facilities, or two, taking the data and using it in other countries; or thirdly, to take the data and use it in—in terms of use as opposed to disclosure—to use it in support of their own registrations

The COURT: Fifteen minute recess.

[Whereupon, the trial recessed for approximately fifteen minutes, after which time the following proceedings were had.]

The COURT: Proceed.

Mr. HEINEMAN: Thank you, your Honor.

By Mr. HEINEMAN:

Q. Just before the break we were talking about the things that can be derived by virtue of disclosure of Monsanto's data to a sophisticated observer, let's say, and you were beginning to discuss that subject. Could you elaborate on it, please.

A. Well, perhaps one of the best ways to put it in prospective is that there are a number of companies out there that are extremely effective in this business, Monsanto being one. If I could see the equivalent of that data over there, or my scientist could see the equivalent of that data for Ely Lilly or du Pont or Dow, we think we would be privy to some extremely useful, extremely sensitive information for [102] the other company instead of seeing what they would see if they saw ours. I can say

that I would certainly be ahead of the game if I saw theirs, specifically in the area of metabolism in which you determine how a product is broken down in the soil or in the plant.

* * * * *

Q. When you were discussing that the successful candidate must pay for the nine hundred and ninety nine [103] unsuccessful candidates, what is the total amount that Monsanto has spent from 1960 through 1981 in developing those successful candidates?

A. So far we've spent over two hundred and fifty million dollars.

Q. How many companies with an investment of that nature, how many companies are involved today in discovering and producing new pesticides?

A. It's probably less than twenty thousand. There's probably three or four German companies, one or two Swiss companies, one British company, two or three Japanese companies. And then the rest of them are in the U.S. And there are probably eight to ten U.S. companies. And most of them probably have an effort that is less than that, or in that range.

Q. Now let me get in for a moment, if I may, to the competitive nature of the pesticide market which you've been discussing. Are there suitable alternatives in the marketplace to Lasso?

A. Yes, there are several good products by some of our competitors for virtually every use of Lasso. We now have developed a label to where there are over two hundred different ways a farmer can use Lasso. When you figure out the ways he can apply it, when he can apply it, in what crops and what other products he can mix with it. And we have [104] several crops, corn and soybeans, peanuts, cotton, a number of other crops. And in every case there is at least two and probably four to five competitors for that use.

Q. Now while I'm sure that you believe that the Monsanto product is superior in each instance, do they compete for that market in each instance?

A. And quite effectively.

Q. Now do you run into any imported products?

A. Yes.

Q. Can you describe those for the record?

A. There are several foreign companies that have extensive U.S. agricultural operations. Bayer of Germany has a company called Mobay.

The COURT: That is extensively advertised right now; is it not?

A. Yes, sir. And a product called Cencor. For many years they made that in Germany. Not too long ago they built a plant in Kansas City. A German company Data Chef sells a product called Basogram and several other products. And the last time I knew about their manufacturing procedures, all of those products were manufactured in Germany. Ciba Geigy, a Swiss company, has two key products in the U.S., two herbicide products, one of them Atrazine and the other one Duo. Atrazine originally was produced in Switzerland. It's now produced in this country and has been [105] for several years. But Duo has been, and still is, I believe, manufactured in Switzerland. ICI, a British company, had a product called Paraquat. And that for a number of years was marketed—or has been marketed here. For a number of years was produced in England. More recently they have a plant here in the U.S. But yes, foreign imports are a factor.

By Mr. HEINEMAN:

Q. Do you compete with these companies overseas as well?

A. Yes, we do, quite heavily. The competition if anything is greater, Australia, Korea, Japan.

Q. And now China I guess is developing?

A. And now China, yes.

Q. What is the effect, if any, of disclosure of your data in terms of your foreign competition overseas?

A. Well, in a substantial number of countries that are key agricultural markets, they have neither the same regulatory procedures nor the same patent laws. In fact, in a number of countries, the patent situation is deteriorating, or are virtually nonexistent. In Mexico, for instance, you have three to five years and you have to put in a—you have to go through some step of manufacture there. The situation is similar in India which obviously is large in the rice market. In some cases they do little about checking as to the source of the data. So that once a company were able to get their hands on U.S. data that was submitted for [106] registration here, that data could be used to register in another country regardless of what you might think about it.

And even in those countries where we might have a patent it is extremely difficult to pursue a patent violation. We have been attempting to get a Lasso patent in Israel for thirteen years, essentially the same patent that is issued in every other place. And we have been unable to do so. The Hungarians have just openly violated our Roundup patent in a number of countries and have made and are making Roundup. And we pursue it as vigorously as the law will allow in those countries; but nevertheless, having a valid patent does not preclude or exclude those people from getting in.

So by virtue of having our data, they can utilize it in other countries.

Q. Now by utilizing it you don't mean they're just referencing the fact that you have a registration in the United States?

A. They're actually taking the data itself, in some cases, or they can take the data itself I should say—take the data per se and cross out Monsanto and write in Chemoplex of Hungary, and go register the stuff.

Q. Now in terms of the nature of the data that we're talking about, can you describe it for us generally, what is it that Monsanto Company submits in support of a registration, in very general terms, initially?

[107] A. Let me see if I can block it off into about five general areas. Let's first start with the most obvious. We have to—resubmit efficacy data that shows how the product is used to control certain weeds. How does Roundup control, what weights it should be used, when it should be used, how it should be applied, how much water, how consistent is it over how many years. And we do this working with universities and our own data. Closely tied with this, if there is a crop you must show crop safety as well. If it kills the weed at this rate, is it safe for the crop at twice that rate or three times that rate. What happens if you splatter it on the crop when you're applying it. What happens if you apply it too late or too early. All these things to determine what the crop safety is so that you can put appropriate statements on the label for the user.

Then working our way back, the environmental information, what is the fate of the chemical in soils. We look at a number of different soil types under a number of different conditions to determine how long does it persist in the soil. Does it move in the soil under heavy rainfalls. Does it stay around too long if it's been extremely dry. And these are very, very thorough experiments going over several years. Because we're required to do all the way from chemical analysis to coming back and growing sensitive crops.

To determine its safety on fish and wildlife there are [108] a number of tests that you must run on various fishes, on things like quail or pheasant or what you to determine its safety there. What happens if the quail ingest it. In some cases, depending on if it's an insecticide, what happens if the quail are in the spray pattern. What happens if the stuff runs off into the water.

Then we move into the metabolism studies, and then you must demonstrate what happens—what is the breakdown product of the material in the plant, in the soil, and to the extent that you can in people. Now obviously you use animals such as a cow or a rat or a chicken in which you feed them amounts of the material in radioactive

form where you can trace it in terms of its breakdown products. Because once you have determined its breakdown products you can then develop a method of analysis for the parent material, the original chemical and the breakdown products to determine how much of it is in the food or the feed and so forth by very sensitive methods.

And that leads you further into the toxicology. There is something—I think the last count bears something like forty different toxicology studies that we run starting with what we term acute. What is the—what amount in a single dose will kill the animal, to fairly short-term feeding studies like feeding large amounts for a month to feeding additional amounts for ninety days to feeding the material [109] for a lifetime of the plant—animal, to going through three generation studies. In other words, if you feed it to rats for several generations you see that each generation is able to give birth correctly and the progeny to the extent that we can determine, are normal. And we measure and observe the generations for any abnormalities, to the so-called chronic mouse and rat studies which are typical ones used that go for twenty four to thirty months. And in all of these studies, extensive pathologies are done, gross. We study behavior, we keep records on the weights, the feed consumed and so forth. Incidentally, probably the field of toxicology has grown in terms of skills more rapidly than any other one. And it's in part due to some material errors made by a laboratory that caused substantial improvement in toxicology.

There is a laboratory, IBT, that did a number of studies for the Government and for the industry, certainly for a lot of our studies. We found out they were doing extremely sloppy work. And as a result of that extremely rigorous standards have been set up on how to conduct toxicology. And so its improved. But at any rate when you then have the toxicology you can determine the effect on animals, both long-term and short-term. And you know how much is present, and you know how long it's going to be there,

and you know how much you need to get done, and you know how much the [110] applicator is exposed to, or the grower exposed to, the farmer and the consumer. Then your regulatory agency can then make the appropriate determination to see if there is sufficient safety for the product to be cleared. So you put all of these together and that represents the main thrust of a petition.

Q. Now all of that data that you submit in support of a registration for a compound, what is your understanding and what is the understanding of the product committee and the Registration Department at Monsanto Company, and the Ag Products Company, as to how much of that is protected from disclosure under the 1978 amendments to FIFRA.

A. Well probably the best way I can describe it, the stuff setting over there on that cart is all the stuff—all the registration data that's been submitted for Roundup alone since about 1973 or '74. That is a whole bunch of uses. The two pages that are open here on this one, these two pages on this petition—which is the formula, and there's a couple of pages on manufacturing data—out of that stack of tens of thousands of pages those are the only two pages, plus the manufacturing, maybe a total of four pages that is held confidential. The rest of it, according to my understanding of the Agency's interpretation of either 3(c)(1)(D) on use, or section 10 on disclosure, all of the rest of that would be available under those particular sections.

[111] Q. Let me hand you what has been marked for identification purposes as plaintiff's Exhibit Numbers 7(a) and 7(b), and ask you to examine those and identify them for us, please.

A. These are pictures of our registration manager, Dr. Serti, who reported to me while I was Director of Environmental Operations, with the Roundup data that has been submitted to EPA for various uses. And it's the same volumes that are shown here. And all of this data,

with the exception of the two pages I indicated, would be available, as I indicated, in section 3 and section 10.

Q. Now if you look at one of those photographs it shows some cabinets in the background with locks on them?

A. That's right, the one which is a head-on photograph directly to the left of the stack. This is—and to the right also you can see the filing cabinets, both the vertical and drawer type where we store our data. And as you can see in our registration area within our agricultural products building we do keep it under lock and key.

Q. Now could you tell us, for the record, a little bit about Roundup; and apply the criteria that you have discussed in terms of target and synthesis and analysis and development to the Roundup situation?

A. We identified Johnson grass as a major target and objective of our screening program in 1952. Every compound that we synthesized we look for to see if it would control [112] Johnson grass. We came up with a couple of near misses in the mid-60's, but essentially did not discover an acceptable commercial product. In 1969 we discovered Roundup, which was seventeen years after we had started looking for a solution for Johnson grass control. In 1974 we got a non-crop use; in other words, for use on railroads and highways and industrial sites.

The COURT: Levies?

A. Sir?

The COURT: Levies?

A. Yes, Sir. No—well, levies are kind of interesting. You can spray on the back side of the levy but you can't spray on the front side of the levy. And that sounds a little bit unreasonable. But in point of fact——

The COURT: The reason I asked the question, prior to getting on the bench I represented a drainage district. And the members of the district, the farmers within the district, if they saw one sprig of Johnson grass the reaction was immediate and violent. Go ahead.

A. Most farmers feel that way about Johnson grass. But when we registered our first crop use in 1976, twenty-

four years after searching, and in 1982 we now have a number of uses for all sorts of different crops, and market it in a number of countries. But the largest use that we think will be the largest use that we will have we still have not [113] cleared, we think the largest single use will be for control of weeds in aquatic situations including Johnson grass, and a number of others for control of irrigation ditches, drainage canals, lakes, recreational areas. And we still have not received that. And it's now thirty-one years after we started looking for the target.

So it's a long-term commitment and the risks are substantial. And we are now putting in more technical resources, both research and development. We now have more technical resources applied to Roundup than we did when we first had our major initial technical effort from '71 through '74.

By Mr. HEINEMAN:

Q. Have you applied, or has Monsanto Company applied to the Environmental Protection Agency for clearance with respect to aquatic uses?

A. Yes, we have.

Q. And when was that application submitted?

A. I'm not sure of the exact date. It was somewhere in the late-70's. It could have been—'78 is probably a pretty safe bet, but I'm not sure of that exactly; but it's been four or five or six years. We tested first on aquatics in 1970, and we have been running tests for thirteen years before we obtained label approval.

* * * * *

[114] Q. (By Mr. HEINEMAN) How exactly does Roundup work as opposed to other herbicides? What is it that makes it unique in terms of Monsanto's estimation of it.

A. We think it justifies the term unique several different ways. First of all it has an outstanding environmental impact in terms of safety to wildlife and safety to things like honeybees and so forth. It also has a good human toxicology picture. It's somewhere between—much safer if ingested than say an aspirin in terms of accute toxicol-

ogy. [115] But most especially, it does the job for the purpose intended. Applied to the Johnson grass, it moves all the way down through the leaves down through the stalks and down into the rhizomes of the underground fleshly parts of the plant, all the way to the very tip. And if the rhizome has a grain part extending above the ground, it will kill it. It will translocate down. It's extremely consistent, and it not only works on Johnson grass it works on quack grass, which is the Johnson grass of the north. It will work on nut sage or nut grass, as they call it. It will even work on woody species like wild brambles and woodrose, and has a broad range of activities. And yet, as soon as it hits the ground, touches the soil, it's completely bound to the soil surface so that you can come back and within—and we've done it in plants, and planted the most sensitive crop you can think of where you have just sprayed Roundup, such as lettuce, and it's completely safe. You can come back in and plant. Or conversely, another thing I'm saying is the soil microbiology, the soil microbes, the bacteria and other organisms in the soil chew it up into harmless components very quickly. So for a collection of reasons it kills the weeds, it's safe on people, it's safe to the environment, it's an extremely flexible tool for the farmer. They have developed what they call wipers in which they can just drag a bar across the top of the soybeans and take out Johnson grass, volunteer corn, [116] or some of these other things. Extremely flexible for the farmer. Its use in tea in India, to rubber in Malayia, to coffee in Brazil, to wheat in England. It's been a unique product.

Q. Do I understand you're saying that it takes care of perennial grasses?

A. I guess I overlooked the most obvious.

The COURT: He didn't use the word perennial yet.

A. A number of herbicides will take care of annual weeds, those that germinate from seeds every year. Lasso will do it. Our competition products will do it. But very few if any will effectively and consistently kill the peren-

nial weeds, those that live from year to year to year and keep reproducing from fleshy underground parts or from stems, or trees themselves. And this product does as consistently for the perennial weeds that a number of products would do for annual weeds.

By Mr. HEINEMAN:

Q. How is it that Monsanto Company has learned the mechanism by which Roundup works within the plant? Is it through the metabolism studies and things that you have done?

A. Yes. We have done a substantial number of metabolism studies to determine the effectiveness. From the metabolism studies we can do a number of things. We can determine [117] if there's anything we can do to improve Roundup's effectiveness. Do we need to change the wetting agent and surfactant, can we change the timing, can we change the rate. And indeed, we have done some of those things to lower the amount that the farmer has to use substantially.

We can also use that as leads for additional, possibly better products than Roundup, new chemicals, not successful—non-successful, but nevertheless, we looked at several thousand. It gives us all sorts of insights into how it works, what we should be doing to build the next molecule, and how do we make the present compound work better.

Q. Have your research scientists done any radio labeling to prove the translocation and enhance the metabolism studies?

A. Yes. We do that routinely. And this consists of making a radioactive version of Roundup and applying it to the plant, and then measuring the radioactivity. And we do this by extremely sophisticated measures. And we're certainly among the leaders of that particular technology where we hook together a number of different scientific devices including infrared beta cameras, mass spectrophotometers, and gas-liquid chromatographs, and so forth are hooked into a computer so that we can deter-

mine precisely what the hunk of the molecule is we're looking at to a greater extent than has been done before.

[118] Q. And do I understand correctly that the information which you have just described as having been generated on Roundup is included in the data submitted to the EPA?

A. Yes.

Q. And that it is not among that which is protected by your understanding of FIFRA?

A. No, it is not. And even though a person were not trying to get his own verison of Roundup labeled, if a person were not utilizing that technique, if they did not have the skills and facilities to do that, then they would see that. And if they had a completely different chemical that would compete with say Roundup or Lasso, then they could utilize that technique to speed up their registration time, so that they would be a competitor sooner or they could do it with four scientists rather than eight, or in essence, reduce the resources that they were having to use, and use those resources then to compete with us in still another turn.

There's all sorts of ways they could use that including registering their own version of Roundup either in this country under section 3, or getting their hands on it for another country through a section 10 disclosure.

Q. You mentioned the factor of time. What is the importance, if any, of time in terms of commercializing a pesticide?

A. I don't believe it's possible to overestimate the [119] value of time. We spend a great deal of our time as management trying to see what we can do to compress the time needed for identification of targets, needed to obtain the data for registration, trying to figure out the most effective way to present it to EPA so that they can be most effective and less time consuming in making their judgments and continuing on.

From the time you get into the marketplace with a new product or new use for an old product, until such time as

you penetrate that market to where it's profitable is a matter of years. It isn't the money that you make on years one to five that make a pesticide profitable, it's the years twelve to seventeen, fifteen to twenty. That's when you've achieved your market penetration. That's when you've reached a steady state in terms of amount of resources you've had to put in there. That's when your manufacturing plant is finally running effectively and efficiently at the lowest cost. So that by the same token, if you get there sooner you got that edge on your competitor. If you get there in three years and he gets there two years later, you have got two years in which you're getting your product accepted by the farmer. You're learning more about your product under farmers' conditions; that old [saying] there's nothing true about time is money. It's just with us it's virtually everything.

Q. Do you have a practical example that you can describe for the court in terms of Duo, for example, as [120] compared to the Monsanto product in terms of time?

A. Duo is an especially effective competitor for our product Lasso. Duo and Lasso both fit in to the same general classes of chemistry, a class that we called acetanilide chemistry. We came out with our first accetanilide chemistry in 1956 with a product called Landox. In 1965 we came out with a second generation with a product called Ramrod. And then in 1969 we came out with Lasso, the third generation. Each time we came out with a new product, because they were in the same class of chemistry we could be more predictive on how much it would take, what crop safety, what the residue procedures should be, what the metabolism breakdowns were, ways of synthesizing the thing, what we should expect on how to run our tests so that each time we came up with a new product we were more effective and moved more rapidly than we did before. As a result, we, for that reason and other reasons, we were the only company to have an acetanilide chemistry from 1956 until about 1975 or '76, whenever it came on the market.

Ciba Geigy in developing Duo ran into some of the same problems that we did back in 1956. They underestimated the level of residue that was expected and indeed showed up in certain parts of the crop plant, particularly silage corn and sweet corn. They ran into apparently some unexpected problems in their metabolism studies. It is my judgment and [121] my estimate that had Ciba Geigy had the knowledge we did about acetanilide herbicides in general, nothing to do with Duo, but had access to our metabolism, our environmental impact studies, our residue studies and our efficacy studies on Randox, Ramrod, and Lasso, that they could have eliminated a substantial amount of time from their commercialization of Duo. By virtue of them not doing that we were in the market without their competition for another one or two years. And as a result we solidified or further strengthened our position in the marketplace. We had a better chance to observe their product and decide what—how we could compete with them. Because they weren't in the marketplace yet, and their costs continued to increase while they were not selling.

So in this case, the competitor's lack of insight hit them in terms of time. It was an advantage to us, substantial disadvantage to them. And one that would have been eliminated had they had access to data equivalent to that for Roundup. And they would have not needed our formulation or manufacturing data at all. That would have been virtually no help to them.

Q. As I understand your description of when Randox, Ramrod, and Lasso were developed, the data that was generated to obtain their registration was submitted to the EPA prior to 1970; is that right?

A. That's correct.

[122] Q. So that what is your understanding of the FIFRA rule with respect to what benefit would be generated to Monsanto Company with respect to data submitted prior to January 1, 1970.

A. It is my understanding that no compensation would be available for any of that data submitted prior to 1970, and a substantial part of our Lasso data, our initial registration for Lasso which we obtained for the 1969 use season, was submitted prior to 1970. So Randox, Ramrod, and Lasso data would have all been available pre-1970 data.

Q. But you heard Ms. Mayer talk in her opening statement in connection with the provisions of the statute with respect to exclusive use and compensation and all of those things. Would they apply at all to the data you have just described?

A. None whatsoever.

Q. Now you mentioned the ability to expand on uses. And could you tell the Court something about that and in terms of using the information that you presently have in your data to get new uses for the product?

A. When you're commercializing a new product you have a finite amount of resources. And you can only approach a certain number of the uses at any one time. For instances, with Lasso we decided corn and soybeans were the most important. And we selected those two crops. But with that there [123] were a number of different ways that this could be applied. And we only picked a couple of those. We said Lasso can be applied to corn and soybeans, the surface, without mixing it with anything except water. We then went back and based on that experience and the precious knowledge, we said another way of applying Lasso is to mix it with Atrazine or with fertilizer solution or by flying it on the plane. And each time we do this we work with the farmers and determine a new form of problems, it forms kind of a feedback. We continue to expand our label to where the original label for Lasso, although it was the proper one to obtain, now represents a very small segment of how Lasso is actually used. And all the rest of the petitions containing these other uses represent the most effective and the most common way that Lasso is used.

Q. Why is it that Monsanto Company works to develop from Randox to Ramrod to Lasso to Machete to Roundup and improved uses?

A. Well, obviously we would like to be our toughest competitor. When our product is displayed we would like to display it with one of our own. The competition is extremely tough out there. We came out with Randox in 1956. Within two to three years Ciba Geigy came out with a much more effective product than Randox. We continued to look for ways of improving Randox. We came out with Ramrod, which was a [124] substantial improvement, it enabled us to recapture and do a better job in the market. In the meantime, Ely Lilly, and now Union Carbide then Amchem, came out with two products in soybeans that were extremely better than Randox. We came out with Lasso in '69 which was a substantial improvement over both Randox and Ramrod, and a substantial improvement over the competitor's.

Ely Lilly then had three competitors come out in the late-60's and early-70's that were certainly tough competitors for their product. And it goes on and on and on. In other words, competition drives you in part and you continue to try to have the best product possible.

Q. Who is the ultimate beneficiary, other than obviously the profit to the company, of this research and development?

A. Well, if the farmers have the same quality of product available now that they had in 1970 they would lose in several ways. First of all the cost of those products as compared to the cost of these products are substantially different because these newer products take less per acre. And the total dollar expenditures are less per acre. They would have to use more of them to get not as good weed control. Yields would be off, consistency would be off. And in some cases safety would be off. In many cases, the products are more evironmentally safe or easy to handle. [125] Randox was miserable to work with. It burned, it irritated, and those properties don't exist with Lasso. But

the ultimate benefactor of all of this real hard competition is the American consumer who is paying a lot for his food. But he's paying less than he would if the farmer didn't have effective means of weed control. And he is still paying less percentage for his food than any other country in the world.

Q. As I understand the EPA is not the only agency to whom data of this type has been submitted by the Monsanto Company?

A. That's correct. Although governments—Japan, France, Germany, Australia, virtually every country, every country that I know of where we sell has some sort of registration procedure. And so we, in those countries where we market the product, we submit petitions so it is submitted to these other——

Q. There are state agencies as well, I guess?

A. That's right. State government, state agricultural—well, it depends on which agency in terms of which state. But we do submit—in some cases the states require only the briefest of indications plus a copy of the EPA registration procedures. In other states such as California we will submit the package to them that we would submit to EPA.

Q. What are the opinions that you and the new product committee and the Monsanto Agricultural Products Company and [126] Mr. Reding who chairs that committee, what are the opinions that you have with respect to the development of the foreign market in terms of what it will mean to the American pesticide producer?

A. Well, it's large and getting larger. And it's getting large in two ways. It's getting larger just from sheer quantity as more and more governments are devoting more and more attention to agriculture and therefore are bringing in the modern units, modern components of agricultural production, including pesticides. But as they do so, the percentage of our pesticide sales that go international as opposed to domestic is increasing. So we see it as of growing importance to Monsanto. And of our products

at least two, two out of our three top products the sales are larger outside this country than inside this country.

Q. Which are those?

A. Avadex BW, which is used on wheat and barley in Canada and in Europe and in sugarbeets in Europe and in Australia; and then Roundup which is used in somewhere between sixty and eighty countries. Lasso is larger in this country.

Q. As I understand it, Machete is used only overseas?

A. That's right, except for the so-called section 18 use in Arkansas and a couple of other States while registration is pending.

Q. How did you come upon Machete as a new product? [127] A. Well, first of all we had, as a target, to try to find something for transplant rice. Transplant rice is where they go out and take the young seedlings and stick them into the rice paddy by hand or by a stick, or even by a machine. Whereas in this country all of the rice is planted more or less as you would plant wheat. It's drilled with the seed into the ground. And this calls for a different type of rice herbicide, one versus the other. And Machete is a very close relative with Lasso. Lasso was a near miss on rice, but every now and then we would wipe out the rice field, we would kill the rice. So we went back and made modifications of the Machete molecule and found out—or of the Lasso molecule—and found out we indeed did have safety on rice. And we registered it in Korea, Japan, and Taiwan.

Incidentally, Japan has every bit as strict a registration procedure as does the U.S. So it's been registered and it's been registered there for approximately ten years. Incidentally, Lasso has a number of five zero one four four, 5,144. Machete is five two eight one nine, so it came along—it was synthesized about twenty seven hundred compounds later in terms of numbering sequence than Lasso.

Q. Do I understand it has a selectivity feature to it in terms of its use on the rice crop?

A. It's safe on rice whereas the other products were not. And it enjoys—it's extremely important in Korea and [128] Taiwan at this point.

Mr. HEINEMAN: Off the record a moment, your Honor. At this point I'm about to embark——

[Discussion off the record.]

The COURT: I have a note here that the agricultural end of Monsanto Company accounted for about seventy percent of its profit.

A. Yes, sir.

The COURT: And then I saw on one of these charts that the agricultural thing only accomplished about fifteen percent.

A. That's of sales, your Honor.

The COURT: Of sales?

A. Yes, sir.

The COURT: In other words, you make more money in the Ag business per unit?

A. Yes sir, four to five times as much.

The COURT: I see.

A. In fact, much to our dismay some of the others have negative numbers.

The COURT: Sir?

A. Some of the others have negative numbers.

Mr. HEINEMAN: For Monsanto Company as a whole, [129] unfortunately.

[Whereupon, the proceedings recessed until Tuesday, March 9, 1982.]

TUESDAY MARCH 9, 1982

The COURT: You may proceed.

Mr. HEINEMAN: Thank you, your Honor.

By Mr. HEINEMAN:

Q. Dr. Carpenter, when we broke yesterday afternoon we were just beginning to discuss the nature of the patent protection available with respect to the products that Monsanto has registered with the EPA. Could you give us some indication of the number of patents issued

to Monsanto Company versus the number of products that are actually commercialized?

A. We have a substantial number of patents. They're in the hundreds if not in the thousands. We obtain patents on those compounds, new chemicals which do not achieve commercialization, a substantial number of them. Because they are indeed new chemicals and they are patentable on the basis of their chemistry alone, in many cases they're patentable on the basis of their activity even though they're not sufficient to be commercialized. And then finally once you have identified a commercial compound you synthesize, make new chemicals around that area of activity that serves as a [130] patent family for that chemistry. So we have a substantial number of patents, and we have had ten proprietary herbicides .

Q. Now you have talked previously about a sequence of events that occur, many of which take place at the same time, starting with the selection of a target and the synthesis of chemicals. Where in that process does this patent situation you've described occur?

A. A patent—you can have a patent issued over a broad range of that time frame. You can have a patent issued within two to three years, even one to two years perhaps after you've synthesized the chemicals. Obviously that could be well before you have commercialized the chemical. In some cases the patent can actually, for any number of reasons, back and forth between the Patent Office and the company, you can have the patent issued after we have obtained the first registration. So I would say that a two to an eight year range after discovery is not an unreasonable range.

Q. Now in your functions as a participant in the new product committee and in the products development for Monsanto Agricultural Products Company, have you had occasion to be informed and study the problem or facts with respect to the patent application on the candidates that you've studied?

A. Yes. First of all, as a matter of routine in that assignment, I routinely receive monthly reports from the Director of Patents for the Agricultural Products Company. [131] Finally in our decisions, or in our discussions in our new product committee meetings, the status and predicted status of the patent of candidates was routinely considered in our processes.

Q. Now after synthesis, once the product is discovered—and by the product at this point I'm talking about the specific chemical as opposed to what is eventually registered as a product—when a specific chemical is discovered how soon thereafter is the application for patent usually made by Monsanto.

A. Well, as soon as possible you file the application for a number of reasons, one of which is competitive. Regardless of how confidential and how tightly we regard our area of chemistry that we're synthesizing, nevertheless, there are very good chemists in other companies who read the same literature and might have the same thoughts. And in several key product cases the patent application filing dates were as little as a few days apart between one company and the other. And they had no—either company had, to my knowledge, no idea that the other one was working on the patent in question So competitive pressure demands filing as soon as possible, because the person with the first filing date usually historically has the best odds of getting the patent.

Q. Now usually how much of a period of time does it take after discovery in order to make that patent application?

[132] A. It can be as little as a few months.

Q. And has it taken longer than that?

A. It has taken longer in some cases as you have to go back and get things in order to file your patent application.

Q. Now then the application rests with the—to which agency do you submit it?

A. We submit it to the U.S. Patent Office. But in addition there are certain guidelines that you must follow to file in foreign countries as well. Foreign patent estate is very valuable as well. And if you do not file within a given time in certain countries after filing in the first instance, then you do not have a valid application. So you're not only considering what your filing date must be in the U.S., you must see how that stacks up against Belgium, against Brazil, against Japan, and so forth, so that you obtain maximum patent protection on a worldwide basis.

Q. Now to follow that thought for just a moment, the patent life in the United States is seventeen years by law; is that correct?

A. That's correct.

Q. That's from the date the patent is issued?

A. From the date it's issued.

Q. All right. Now how does that compare with respect to the patent laws in other nations in the world?

A. Well, there's no other nation that provides the—[133] any better length of coverage or patent system. There are some that are equivalent to that. Canada is in the same range, more than likely. However, the patent system in some countries is virtually non-existent to being as little as three to five years. So that the patent situation and the ability to have a patent, a workable patent sometimes varies greatly from one country to another.

Q. Now how long does it—in your experience does the patent application rest with the U.S. Patent Office before the patent is issued?

A. A year is probably not a bad number. We've had some that issue very promptly, we've had some that have dragged out for several years.

Q. Now what is the relationship, if any, between the patent development and application process and the receipt thereof, and the registration process?

The COURT: With EPA?

Mr. HEINEMAN: With EPA; yes, sir.

The COURT: All right.

A. Well, by and large they're mutually exclusive, except to the fact that if you lose a patent—let's say you get rejected on a patent and you do not have a patent, then it would call for a reassessment of whether you would wish to go forward with the registration process. But the efforts that are utilized to obtain a patent registration are [134] completely separate operations and require different data, different people, for the most part.

The COURT: Well, in a nut shell is it a fair statement that the patenting process is considerably less time and money consuming than the registration process?

A. Yes, sir, probably by a couple of orders of magnitude.

The COURT: All right. Go ahead.

By Mr. HEINEMAN:

Q. Now you discussed briefly the subject of doing synthesis around the patented chemcial. Would you describe that a little more specifically?

A. May I use the chart here?

Q. Please do.

A. I think it can be seen a little bit better. We have a product called Lasso which was a very important process—product. It has a—it's 2,6-diethyl-N acetylchloride. Now then, this was a compound that we had patented. Anyway, what we can do is when we find that this is an active compound—these are ethyl groups if you will on the 2 and 6 position. Well then obviously you want to know what happens if you stick it at this point, or this point, or this point. Or instead of sticking ethyl groups, what happens if you stick methyl groups or any number of things. And if this is a CH_2, what happens if—in other words, you can change various things all around this ring and leave most of the others.

[135] Now we synthesize by varying this, this, and putting it in different places; varying this, putting on groups up here on the nitrogen. We made all sorts of changes.

Now in some cases we solved compounds that were one-half as good as Lasso. Now obviously we couldn't afford to commercialize a compound that was only half as good as Lasso.

Let's say it takes eight pounds of this material where it takes four pounds of Lasso, or four versus two. Now then, obviously we're better off—everybody is better off to commercialize Lasso and leave this on the shelf. But had a competitor found this product, this product would have been worthwhile for a competitor to develop.

Let's say that in general it's one-half as good as Lasso but in one specialized use for say four million acres of a target, it's equal to or better than Lasso. You can't say it's better across the board. The biological activity, the marketplace, the complications of farming are such that it could have found a market niche where it could have competed effectively with Lasso for a narrow segment of the Lasso market. And a competitor could have seen its way clear perhaps to commercialize that product. But if we have a patent on that product we essentially have provided ourselves patent protection for this one. And this is routinely done in the field of drugs, in the field of equipment, in the field of pesticides. In other words, you get what the patent lawyers [136] call a patent estate. And the Lasso patent estate is very valuable to us.

Q. What do you call the additional product that is one-half as effective as Lasso in most applications. Is that an analog?

A. That would be an analog. In other words, it is—in fact, you can have both analogs and homologs; analogs meaning that it's the same in function and you modify some groups substantially. And homolog would be one in which we just put in more carbons here. But we have all sorts of analogs primarily as a part of our patent estate.

Q. When you obtain the patent you obtain the patent to cover not only the specific active ingredient but the analogs and homologs of that active ingredient as well?

A. The patent for a Lasso or for other product may start off by saying I claim that I have invented a class of compound in which I have a benzene ring. And instead of naming the particular one they will say that is R_1, and that is R_2. And they will say R_1 composes all of these chemicals and they will say R_2 composes all of these chemicals.

Q. Now please be specific for the record and when you talk about R_1 and R_2 what are you describing?

A. These are the positions on the—two position and six position of the benzene ring.

Q. Where once you had an ethyl group you will say—[137] we will say not only an ethyl group but its types of groups that might go in that position?

A. That's right. Now and then they will maybe say the same thing. They will say—and they call these generic formulas, and they will claim those. And that will be their broadest claim. And that's the one that obviously Monsanto or Dupont or Dow or whoever wants to get.

Then they will make other claims down the line and in which they will become more narrow and more specific on their claims until finally one of the claims will identify the specific chemical, Lasso. And in some cases you get the broadest claim that you made. I have a generic formula that will cover literally hundreds of compounds. In some cases you get only a compound, you get the compound itself and nothing else, and that's all you get.

But in addition to that single compound—now once again we go back and even after the patent is issued we continue to look in this area for analogs and homologs and obtain additional patents on those. For instance, once again we say this was the acetanilide family. We probably had at one time two to three hundred patent deals in the acetanilide arena, of which only about four to six actually applied to commercial products per se.

Mr. HEINEMAN: All right, sir. If the Court please, I'd like to mark this so that we can identify these [138] drawings that he might make. And for the record, the drawing

which Dr. Carpenter has just made in terms of the Lasso patent discussion I will label plaintiff's Exhibit 36.

[Plaintiff's Exhibit 36 marked for identification purposes.]

By Mr. HEINEMAN:

Q. Now can you describe in general terms how the registration process with EPA is different from the patent application process?

A. Well, the patent application process in some cases does call for a certain submission of biological data. You do have to say, if I'm claiming this product for control of weeds you say I hereby tested it and so forth. So if you looked at it this way, if you said you had a circle here and all in this circle included all the data you put for a patent, okay, now you would have to show the chemistry and you would have to be quite specific about how you synthesized that chemical. I took so many grams of this and so many grams of that and I recrystallized it and I determined its purity and its structure by these means. And you would have to give your proof. And maybe let's say you might have to talk about a little activity. And that would essentially be it. And you would have to maybe quote prior history as to why this particular product is unique. You would have to talk about the uniqueness of its and you would have to do the literature.

[139] Q. Do you give any physical properties?

A. You would give melting point and you might put boiling point. And you would talk about its soluble in alcohol, its soluble in acetone. In other words, you would give physical properties.

And by and large all of this is published—and the patent itself, when the patent issues—all of this is published and is a matter of record. When the patent issues it's on the patent itself and is published in the patent. Now if you looked at all of the data that deals with registration then if you drew another circle, what I'm trying to point out is there is a tiny bit of overlap in that data you submit to EPA or other regulatory agent for a pesti-

cide registration, and the data you submit in a patent. There is some overlap. For instance, you obvioulsy submit the chemistry of the material, would be in the same place. And you put—you don't talk about proof, whereas we talk about maybe a little bit of activity in patent, we might submit one or two greenhouse studies that are fairly simple to claim the patent. Whereas in our first Roundup petition for crops, for instance, we submitted twenty five hundred experiments that went on in many cases for over three years.

Q. The latter being to EPA?

A. The latter being to EPA. So efficacy is probably a hundred to a thousand times greater, and maybe even more [140] than it is in a patent. Now so that might fit into part of the overlap here. But the metabolism, the toxicology, environmental chemistry, most of the efficacy, virtually all of the crop safety and the things that are in the non-overlapping part where they're mutually exclusive, number one, represents ninety-nine percent plus in terms of research effort of the total package. In other words, there is less than one percent overlap if you looked at the data.

Q. Between what is submitted to the EPA and what is submitted——

A. And what is submitted to the patent. And further if these were—if the size of the circles indicate the total amount of effort, this circle would probably be at least a hundred times greater.

Q. By this circle you mean?

A. The EPA registration effort takes a hundred times more data and effort than the patent. Now obviously you start with the patent. And it's extremely important, extremely valuable. It's critical. But in terms of total amount of effort, one is substantially more than the other. And the main thing is, except for these little areas in here they're essentially mutual exclusive. The effort, the dedication, the people involved, the whole thing is separate from this, from the EPA's.

Q. All right. Now the patent information that is [141] submitted is disclosed to the public if the patent application is granted?

A. That's correct.

Q. And the EPA information, but for the 1978 amendments to FIFRA, is not disclosed; is that correct?

A. At this point in time speaking for Monsanto data, at this point in time this is not disclosed.

Q. By this you mean the EPA data?

A. The EPA registration data.

The COURT: Now you're talking about this amendment. Is that—enlighten the court on this compensation business. In other words, we've got a registration, and assuming arguendo you've got a disclosure, and assuming arguendo that the me-too people, the me-too people or whoever use it. Is that where this compensation comes in?

Mr. HEINEMAN: If your Honor please, may I have the witness describe it? Because he knows a great deal more about it than I?

The COURT: I think that's got a little more to do with the law than some of the things we've heard. I'm not questioning—but let's get into that.

By Mr. HEINEMAN:

Q. Dr. Carpenter, please answer.

A. First of all the data is divided as to whether compensation is available based on the time it's submitted.

The COURT: There was none prior to '70; is [142] that correct?

A. The way the law currently reads there is no compensation for data submitted prior to 1970 which comprises all but one—most of the data for all but one of our products. The person that wishes to utilize our data has to write to Monsanto and notify EPA saying we hereby offer to compensate you for your data. He does not have to say I offer you x-dollars or make—all he has to do is say I offer you compensation.

The COURT: In other words, he might just buy you a glass of milk or he might buy you a ten course dinner?

A. His concept of what's reasonable is all he has to have in mind. Now then, EPA is obliged by the law without waiting to see, you know, if he says I'll buy you a cup of coffee and you say I want the national debt, well, you know, obviously there's no agreement there. But nevertheless EPA is obliged to register the product for the metooer whether agreement has been reached or not. If agreement cannot be reached then it must be referred to binding arbitration for which there is no appeal.

The COURT: Well, when does this take place? In other words, I assume that the purpose of the binding appeal and the arbitration is to establish the nature and extent of damages, if any; is that a fair statement?

A. That's correct.

[143] The COURT: Well, we're getting into speculative damages, we're getting into various rules that apply in court. I don't know about these arbitrators, but if we're talking about the future you can talk about future damages, you can talk about speculative damages, you can talk about loss of business damages. The field is rather wide. And the question is, in your experience—and of course I'm sure both sides will refer to the law as it's written—but it would appear to me that there have been a lot of damage suits down through the history of jurisprudence where the amount involved could have changed substantially, depending on when the matter was presented to the court or the arbitrator. And that's what I'd like to hear about.

A. Well, to my—Monsanto has no experience on arbitration. We have not had a situation—by virtue of our lawsuits we have not been involved in that.

The COURT: You're talking about this lawsuit?

A. Yes, sir.

The COURT: Never been involved in previous years on other matters?

A. No, sir. It has not happened in previous years, to my knowledge, prior to the passage of '78.

The COURT: Well, then you're not in a position. The Court will have plenty of law in the cases, I'm sure, that counsel will be submitting plenty of that, or have [144] already.

The question is, you have no practical knowledge of what the results of arbitration have been; is that correct?

A. That's right.

By Mr. HEINEMAN:

Q. You mean insofar as Monsanto is concerned?

A. Yes, sir.

The COURT: Well of course I'm not asking him to go to American Cyanamid or something like that. They might not have any information either, I don't know.

Mr. HEINEMAN: Well, there may be more public knowledge about that subject. That's why I——

A. Well, the only case of arbitration that I know of, and my knowledge is——

Ms. MAYER: Your Honor, I object.

The COURT: Sustained. I was just asking him—we're talking about Monsanto and not somebody else.

A. It has not happened to Monsanto.

The COURT: Go ahead.

By Mr. HEINEMAN:

Q. Now Dr. Carpenter, according to your understanding of the statute for what is the offer to compensate made? Is it for use, disclosure, or what?

A. It's for use. It is not for disclosure.

Q. According to your understanding of the statute is there any offer to compensate at all required in terms of the [145] disclosure provisions of the statute?

A. There is none.

Q. Now if we may talk about, for a moment, this patent data on the one hand versus EPA data, or registration data on the other. When the patent expires is the data submitted to EPA in support of a registration disclosable by the EPA by virture of the fact that the patent on the product has expired?

A. The patent has no bearing on whether the data is—that's two separate issues. EPA——

The COURT: In other words, if you've got a patent beginning in 1960 and a subsequent registration, and the patent expires in '77, has absolutely no bearing on your relationship or the disclosure as far as EPA is concerned; is that right?

A. Yes.

The COURT: All right. Go ahead.

By Mr. HEINEMAN:

Q. Now you were discussing previously the various periods of time within which the patent may issue as opposed to when you get your first registration with the EPA. Now would you expand on that a little bit in terms of when those times can occur with respect to one another.

A. Well, by and large there is, because of the length of time that it now takes to complete the registration [146] package and put it together—which is now in the range of approaching six years—toxicology alone is forty-eight to fifty-three months—so by the time you submit the data and get your label back—your first label not your subsequent labels—that can easily be six years and in some cases it's stretched on for longer than that. So that the probability is that the patent is going to have issued based on history of patents issuing and the time elapsed, the patents are going to have issued well before the registration—first registration is granted. So that in essence, by the time you are legally allowed to sell by virtue of the registration, you have lost a significant part of your patent life. And a point I would make here is you never lose the first four years of your patent, you lose the last four years. The first four years you always got. If you get your registration your patent has been going for thirteen years, what you've lost in terms of patent protection while you're selling is year fourteen through seventeen. And it's in those years where you have built up the large sales volumes and so forth, where you have an opportunity to recoup your losses.

Q. Now I think you said that there are occasions when the patent application may be granted even after the date of the first registration. So for that particular use that's registered you would have the complete patent life?

A. That's correct.

[147] Q. All right. But I think you testified yesterday concerning Lasso and the fact that additional uses have been registered. What is the effect of that in terms of the patent life?

A. Well probably the most important use we have of Lasso right now was developed in 1979, some ten years after we had commercialized, and some seven years after the patent issue. This use, this conservation tillage use is a way of applying Lasso to prevent soil erosion and at the same time give effective weed control. And it probably now accounts for twenty—maybe up to forty percent of our sales in that use. Now we will have—and it is not—obviously that is not a patentable use, but it's part of our registration, our label packaging data. That will have approximately ten to twelve years protection under our patent. Our patent expires, I believe in 1989.

The COURT: Let me ask a question here. If you don't get your registration you don't sell; is that——

A. Yes, sir.

The COURT [continuing]: —basic?

A. Yes, that's right.

The COURT: But let's assume that you have in your application for registration given certain facts and data which, if disclosed, might cause some problems in a related area.

[148] A. Yes, sir.

The COURT: Now I know you all are going to tell me what the law is. I already understood there might be a difference of interpretation of certain facts, and I'm sure there might be different interpretations of what the law provides. But what I'm getting at here is under those circumstances—and you can't sell it because you haven't got it——

A. That's right.

The COURT [continuing]: —but is there any disclosure problems in that area?

A. No, sir. They do not—cannot, under the law disclose only after registration.

The COURT: In other words, nothing goes until there's registration?

A. That's correct.

The COURT: Well, I would like to hear from both sides on the logic of EPA's position in that area. Not testimony, sir, I want—this is one for the lawyers. In other words, and tell me if I'm getting far afield now and don't hesitate, you won't hurt my feelings—but you've got something that's not saleable that might have a bearing. It cannot be disclosed period. But you get something that is saleable where according to this witness' testimony, more than a few hours, a few days, a few years and a few dollars have gone into the testing and the application for [149] registration and everything else. And the minute you get something that has an enhanced value because there is a probable market for it, or at least a possible market, then it's disclosable?

A. Yes, sir. It's a little bit more—in our viewpoint, it's a little bit more frustrating than that. Let's say at such time the data is disclosed to a competitor and at that point in time that competitor can have, for all practical purposes, the identical label that we have, the hundred or two hundred uses that we've developed for that product, at whatever point in time it comes in it can rely upon all of our data to get all of our uses. And it doesn't stop there. We can say okay, you're where we are, we will compete head and head. But we will apply our efforts and we will find even better ways to apply Lasso, more effective ways, safer ways, and we will submit that. And the instant we submit that they say, by the way, I'd like to cite that data as well. So that in essence, you're technology is not compromised, if you will, in my viewpoint, for a given point in time. You can never take your technology

and protect it for a product such as Lasso, since it's excluded now from any consideration for data or exclusive use. Under the current laws anything else we do for Lasso, improve it for the farmer, to improve our own economics, or whatever, that data is instantly available for as long as we choose to submit data. [150] And all somebody has to do is say we offered a reasonable compensation; and it's there instantaneously, long before any money changes hands or it gets to arbitration.

By Mr. HEINEMAN:

Q. Now Dr. Carpenter, I'd like to discuss—or I'd like to have you discuss for the record the relationship between the cash flow that the company receives in spending on a product as they're developing it, and then when they start to sell it, when they start to recoup that cash flow in terms of the patent life and the registration?

A. All right.

Q. I may not have articulated that very well; but I'd like you to describe that for the Court.

A. What I'd like to do is try to sketch this out on the board. But before I go up I would say this, the expenses you have—and we'll deal not with the backup but with the expenses of the failures, and we'll talk only about the expenses of the compound itself and in a general philosophical term—your expenses start out in a rather modest way. You've got the expense of the synthesis chemist who in his laboratory makes the compound, and the biologist and the greenhouse that tests it. So that the first year your expenses are essentially whatever proportion. If you tested a thousand compounds and you got a winner the first year in whatever it costs you to test those thousand compounds your expenses might be one thousandth of that. That's a little [151] oversimplification, but it's in that range. But if you identified it as having potential and you started those various clocks running, if you will, then the expenses start to accelerate at a very rapid rate. The other thing if we talk about expenses we ought to recognize there will be no income until you

obtain that registration. And for practical purposes, we can use a figure anywhere six or eight years from the time the expenses start until you start getting money back in. So that's the type of thing that one ought to keep in mind.

The COURT: Let me ask a question here. Assuming—now assuming you have got your registration.

A. Yes, sir.

The COURT: You don't know you're going to get it, I assume?

A. No, sir.

The COURT: Is that the trigger that you're talking about, clocks, is that when the clock starts on building the plant or plants and securing the machinery, I assume?

A. You got to do that ahead of time.

The COURT: The machinery is tailor made?

A. You got to do that ahead of time, sir. It's a rare product that won't call for special equipment.

The COURT: In other words, you're gambling [152] that you get registration; is that what you're saying?

A. Yes, sir. Once again.

The COURT: All right. Go ahead.

A. If we spent this in terms of time, and this was dollars and we took a line, and this was zero, when you're over at that line you're at a break even on any given compound. And if we say one, two, three, four, five, six, seven, eight, nine, ten, the first year you're going to spend a fairly small amount. But if it looks good you will spend substantially more than that the second year. You will go like this, because you're going into more complicated tests. You have now got to have several chemists synthesize much larger amounts for the advanced testing. You're starting some of your toxicology studies. Your process people that are trying to figure out how to make it in a big plant are beginning to take some preliminary looks at it just on a look-see basis, because you got to remember there's probably ten—at this point, this is in a

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category of the third year—you probably identified this thing as we're going to go all out on the thing. And at this point in time you start a substantially large amount of toxicology. You're starting your environmental chemistry, your metabolism. You're actually going out to probably dozens, in some cases hundreds of academic cooperators. You have really pulled the plug, and it's going to go even—the line is going to go even [153] further down.

Now then if the third year looks good, at that point in time you probably got to make a commitment for capital investment. You have got to start building the plant, because from the time you decide—now let's just say for the sake of argument somewhere between six and eight, so we'll say that this is the point that you get your first label registration, we'll just arbitrarily say it's seven years after you have found the product, and that means that you had to submit it somewhere say a year, five and a half, because you have got to allow probably eighteen months for the EPA to review the data. That means that—and that's really pushing if because that means you're trying to do a whole bunch of things in five years.

The COURT: Well, does the EPA from the standpoint of their technical approach to this matter, or these matters, do they have the hothouses and the greenhouses and the chemistry labs and a comparable amount of expertise and manpower—or personpower, pardon me—to get into this?

A. They have not greenhouses, they will contract with appropriate academics occasionally just as a spotcheck. For instance, we make claims for one of our products, Ramrod. They will pull a sample, one of their inspectors will pull a sample of Ramrod, have it tested and say you claim that Ramrod will control foxtail under these conditions. Indeed it did prove it, but more importantly not as much biological. [154] They will look at our analytical methods and say, you say your methods will detect this stuff in crops down to this level of sensitivity. Now we want to see if this method is valid. So they have scientists that are capable of doing that. But by in large in terms of

being able to test every product, or duplicate what we did in terms of toxicology, metabolism and so forth, they in no way approach that sort of resources. Spotchecking us and seeing that we're valid is probably a better interpretation.

The COURT: Go ahead.

A. In year three or four then coming back to capital investment, we know from the time that we can make a decision on capital investment—and in many cases, now the last Roundup plant we built, I think, was around sixty million dollars. The first Roundup plant we built was somewhere between twenty and thirty million dollars. Just inflation alone runs it up. But at any rate, that went to thirty million dollars. We know in order to build the plant and get the appropriate permits, environmental impact statement, to get the approved discharges and so forth and so on, the air permits and so on, we're really pushing it if we think we can do all that in three years. So if you say I don't want to put sixty million dollars out into—on the table until I know I got a registration, well, you've avoided the risk but you have delayed when you can actually start making it to three to four years after [155] your registration. Because you don't have a place to make it. So in addition to gambling on starting all the metabolism, toxicology and all these other things, you also have to make a commitment on capital investment.

Now once you start making a commitment on capital investment your line goes straight down. So in essence, what you've got then is, if you would say that your curve then is going to start off kind of like this (indicating), it's going to hit bottom here. But it doesn't immediately jump back up because if you look at sales, your sales start off slow. I remember quite well because the future of our company depended on Lasso. The first year we sold Lasso, in 1969, it just so happened we sold an even million gallons of Lasso. The next year we sold right at two—something less, it was actually about 1.8 to 2 million gallons.

The third year we went to 3.2, and the fourth year we went to 4 to 5. And after that it gets a little bit hazy.

* * * * *

So that even though you've started selling, you've got a pretty slow curve to where you recover. In other words, your net cash flow is going to stay negative long after you have got your registration.

[156] The COURT: Did I understand you to say that the Lasso success story, which I assume you call it that——

A. Yes, Sir.

The COURT [continuing]: —was the financial increment that saved Monsanto.

A. Yes, sir. Well, let's put it this way. If it hadn't been for Lasso and for Roundup in the last three years I wouldn't want to have to compare what my salary might be or where I'd be. Because——

The COURT: I'm not just talking about agricultural——

A. Oh, no.

The COURT [continuing]: —I'm talking about the whole business.

A. Well, sir, let me give you some figures. Last year——

The COURT: That's the reason I think the courtroom is probably being sealed.

Mr. HEINEMAN: That's part of it, sir.

A. Last year our sales were around seven billion dollars for the corporation. And this is a matter of public record, obviously. The Ag Company sales were around one million dollars, something more than that. If you look at Monsanto's total net profit we returned something like less than five percent return on our sales. And our investment is [157] about the same. Our net investment just happens to be about the same as our sales. So we earned five percent return on investment. If you took agricultural sales out of that, we would have returned less than one percent on our sales or investment.

Now when you look at obsolescence, replacing your plants, allowing for inflation, whatever, you can't sustain

a capital intensive company like Monsanto on one percent on sales. So I'm not saying we would go under, but it sure would be a pretty miserable grim place if it hadn't been for Ag.

The COURT: Go ahead.

A. But in summary, you can say that to recover your net capital cash flow from a given product, looking only at expenses for the registration and for the manufacture and formulation and all of the other company sales expenses, development expenses and so forth, you are several years after. It doesn't make any difference whether you're talking about four, six, or eight, you're several years after your initial registration in sales before you can recoup your money on that particular investment.

Now the other thing to keep in mind is that you have still got all of the greenhouses and all of the chemists and all of the biologists that are still back looking every year at those other nine thousand nine hundred ninety nine. And sooner or later you have got to have enough of these products [158] coming along so that they're well up into here (indicating), that can pay for those failures that you're going to continue to find.

By Mr. HEINEMAN:

Q. At what point in your experience does or has Monsanto tended to break even on a product insofar as just the expenses for that product?

A. Probably the third to fifth year, maybe sixth year depending on what the product was. On Avadex——

Q. That's after registration?

A. After registration. On Avadex we commercialized that product in 1961, '62, '63, somewhere in there; and we miscalculated there on how well the farmer would adapt to our product. And there we didn't get to break even until 1970. As a matter of fact, when we started our agricultural effort in 1952 in the old organic division, we formed the Ag Company in 1960, and we were 1962 or '63 before the Ag Company could show a profit. So that the

total Ag effort had a ten to twelve years lag time before it became profitable.

Q. If one were to assume that you got your patent in the second year after discovery, and registration in year seven, all right——

A. Okay.

Q. [continuing]: —when do you break even in terms of when your patent life runs out?

A. Well, if you get it in year two then it goes out [159] in year nineteen. Two plus seventeen is nineteen. And if you're at the break even point at, let's say four years after registration, and you got registration at year seven, then at year—you're at year eleven. So that you're really at a break even point for six years of the remaining patent life. And that is the most optimistic way of looking at it.

Q. Now of course on occasion as you mentioned, the patent can be obtained at or about the time the registration is obtained?

A. That's right.

Q. So you would break even much earlier in the patent life under those circumstances?

A. That's correct.

Q. Now has it ever occurred, Dr. Carpenter, that there could be a delay in registration?

A. Yes, sir.

Q. Okay. Has Monsanto had that experience?

A. Yes, sir.

Q. Okay. How much of a delay can there be with the EPA in getting your registration?

A. There can be several years delay.

Q. Now what do you mean by several years?

A. Well, we have a product, Machete was the fourth generation of acetanilides. This is used for transplant rice in other countries, that we began selling in about 1970 or '72 [160] or '73 in the Far East. I think we submitted that product for registration in EPA in 1977 or '78, and we still do not have registration for that product.

Q. Now let's assume that you had a couple of years, a two-year delay in registration. Now does that have any effect on the expenditures that you've undertaken, anticipating registration at the seventh year?

A. Yes. Virtually all of the expenses keep going unchecked. Now you've built your plant so you aren't going to continue to build more of a plant. But nevertheless, you have got idle capital, if you will, idle capital charges. The plant is setting there and not running, so there are substantial expenses involved in idle capital. But in addition, the people that you—if this was your first product you have got salesmen sitting around with nothing to sell. You're going to continue—the development crew are going to go out and put out their own tests and work with the university and farmers one more year. You have got the whole organization and all the expenses accompanying them sitting there if nothing else, just all the money you have expected, that is now a negative factor, that is impacting further just from the interest that accrues, you know, you owe it to somebody, if you will. You might owe it internally, but nevertheless the expenses get substantially worse.

Q. Now what does that factor of say a two-year delay [161] in the EPA registration do to your economic curve and the time of your recovery?

A. It deepens the curve, it deepens the curve because you owe more, or you've spent more and then obviously it takes you longer to get out there. Now if you have a competitor, and you virtually always do, who's out there, it means it's going to be tougher for you to get into the marketplace just as it was for say Ciba Geigy to get in against Lasso. It's going to be tougher for us to get into the Lasso—or get into the marketplace with a label delay. Now then that means that what you once projected as a market share, that you were calculating this on the market share, is either going to take you longer to get there or you're not going to get there. So you get caught

two ways. You spend more and you run the risk of not having as big a reward out at the end.

Q. So is it possible under those circumstances that you never do break even?

A. That's right. And then you end up dropping the product. This Machete situation, I indicated a company called Chevron has a product called Bolaro which is a rice herbicide. We have been competing, if you will, in the testing arena with the rice experiment stations for Bolaro for quite a while. Just this year Chevron obtained tolerances and thereafter a registration for Bolaro. Chevron, [162] unless we get our registration some time before the next rice season—and it's almost too late now, the season is on us—Chevron will have a minimum of one year's jump on us in the marketplace. It's a good product, they're a good organization. They will be tough to compete against having that one year jump against us.

The COURT: Fifteen minutes.

[Whereupon, the trial recessed for approximately fifteen minutes, after which time the following proceedings were had.]

The COURT: Go ahead, counsel.

Mr. HEINEMAN: Thank you, your Honor.

Q. (By Mr. HEINEMAN) Dr. Carpenter, pursuant to your understanding of the 1978 amendments to FIFRA, is there any relationship under the law between the offer to compensate from a me-too applicant and the actual damages or expenses or investment that you have in the product that you have registered?

A. It is my understanding——

Ms. MAYER: Your Honor, I object. I don't think there has been any testimony that they have had any experience with offers to compensate. And I think his testimony will be speculative.

The COURT: Well, in view of his previous [163] testimony I'm going to allow him to testify briefly on the matter. Go ahead.

A. The statute does not provide any recipe, if you will, for determination of damages. It merely says that an offer to pay must be made and that if agreement cannot be reached then it must be referred to arbitration, without giving procedures, techniques, or guidelines for determining what if any compensation must be given.

By Mr. HEINEMAN:

Q. Okay. Let me take a moment if I may, here, to have you identify these documents that you have prepared in illustration of your testimony. The first one which we marked plaintiff's Exhibit Number 36, would you for the record state what that document is?

A. In general it was a discussion of how patents are arrived at and the type of patent we have, and how we—why we pursue patents with pesticides.

Q. And it was a discussion of the analogs that are covered by the patent application?

A. Analogs, yes.

The COURT: Pardon me, getting back to the witness' objected to testimony, I understand it to be that there is arbitration, that the arbitration is final and binding?

Mr. HEINEMAN: Yes, sir.

The COURT: And that there is no appeal [164] whatever? In view of the objection I think that that question probably is better left up to the Court rather than the witness. You may proceed.

Ms. MAYER: Thank you.

By Mr. HEINEMAN:

Q. If I may turn then to what's been marked for identification purposes as plaintiff's Exhibit Number 37, would you identify that for the record, please?

A. That shows the composition of the items that comprise patents, the various data that is in a patent as compared to the data or scientific information that is in the registration document package that is submitted to EPA. And I pointed out there is a very tiny overlap between the two areas of endeavor.

Q. All right, sir. And going then to what's been marked for identification purposes as plaintiff's Exhibit Number 38?

A. We showed in general in Exhibit 38 that the expenses involving the registration of a candidate pesticide start off slowly and accelerate to a peak in registration, to the point in time of registration, and that you do not obtain what is used as a term, a positive cash flow, until several years after registration.

Q. Now Dr. Carpenter, there has been a good deal of discussion in the last day or two concerning active [165] ingredients, technical product and formulation. Now for the record would you differentiate between those terms?

A. Let me use Lasso as an example. The active ingredient in Lasso is a chemical called Alachlor, the one whose structural formula I drew on the exhibit. The technical product is the manufactured product that has a certain percent purity, usually above ninety percent, with a certain amount of inactive or non-pesticidal ingredients that are a part of the manufacturing process. So that the technical product is composed primarily of the active ingredient and a bunch of other glop, if you will.

Q. A bunch of other what, sir?

A. Miscellaneous things. The formulation is that product which is—well, actually, you register both the technical ingredient, but you register the formulation and that is the product that is sold to the farmer. And that includes a known guaranteed amount of the active ingredient plus other components that also are identified that give the qualities that you want. You have a solvent perhaps to dissolve the pesticide. You have emulsifiers so that you can mix the two with water or fertilizer solution or some inert carrier, even clay. And usually the formulation is expressed as pounds per gallon. In other words, Lasso is sold as a four pound per gallon formulation. In other words, it contains four pounds of [166] active ingredient per pound of formulation.

We sell a granular form, a Lasso 2 that is fifteen percent active. In other words, for every fifty pound of product you buy in a fifty pound bag it contains seven point five pounds of active ingredients, it's fifteen percent active.

Q. Fifty percent?

A. Fifteen.

Q. Fifteen?

A. So that the formulation then contains known designated planned ingredients over and above the active pesticide.

Q. Now [illegible] formulation, the formulated product is what is eventually sold to the consumer?

A. That is correct.

Q. And it contains the active ingredient plus——

A. Solvent, emulsifier, carrier.

Q. A surfactant to spread it over the weed, plant——

A. Right.

Q. [continuing]: —or something like that?

A. Yes.

Q. And those are labeled on the label as inert ingredients?

A. That is correct.

[167] Q. Now in connection with the development of a formulated product, how does the research and development department coordinate with the technical services and the various other departments; how does this product move along in terms of development prior to registration?

A. Well, at the early stages the formulation section studies the active ingredient to determine the best way that it can be applied. Factors that it must consider are obviously safety. You must not use solvents or other materials that are extremely toxic. You must consider the fact that they are registered as inert ingredients with EPA. You must consider costs. You can't use exotic or expensive solvent that would increase the cost substantially.

Primarily you're looking at effectiveness, in other words, how can the pesticide be applied to give the best results for what you intend to use it for. Shelf life, it must be able to sit on a shelf in a farm market store for *x* number of years and still be active and handle properly. All of these factors must be considered. And as you're going through the preregistration stage you are probably testing several different types of formulations. And you will select one of them, or maybe more than one, to be that which is registered.

Q. All right. Now this comes subsequent to the [168] synthesis stage itself?

A. Yes, yes.

Q. Now, Dr. Carpenter, I'm going to hand you what has been marked for identification purposes as plaintiff's exhibits 4-C and 4-M, and I wonder if you would examine them in turn and describe them for the Court, please?

The COURT: Has opposing counsel seen them?

Ms. MAYER: We have copies, your Honor.

The COURT: All right. Go ahead.

A. These two photographs are pictures taken in our formulation laboratories, two of our laboratories, which shows you some of the complexity of the work that's done to obtain proper formulation.

By Mr. HEINEMAN:

Q. Now let me hand you next what has been marked for identification purposes as plaintiff's Exhibit No. 4-J, and ask you if you would examine that and identify it for the Court, please.

A. This is one of the shelves of our sample room that contain the samples that are being—in part, some of the samples—I have to make a count there—that are being looked at by our research group at any one time. These can be all the way from batches of process studies to new chemicals themselves. Typically these will turn [169] over at a pretty rapid rate, and there will be several shelves similar to this.

Q. Now the exhibits you have just identified here relate to the synthesis and formulation chemistry aspect of Monsanto's business; is that right?

A. Yes.

Q. Now subsequent to synthesis of the chemical itself you then proceed into screening; is that right?

A. That's correct.

Q. Now let me hand you what's been marked for identification purposes as plaintiff's Exhibit No. 4-L, and ask if you would examine that and identify it for the Court, please.

A. This is a typical greenhouse of which we have many, in which we grow the plants for various types of testing. In this case this is a screening greenhouse in which we will look at a large number of plants grown under identical conditions, looking at the impact of the chemical on these particular plants.

Q. Now where is this particular facility located that is represented in Exhibit 4-L?

A. This is in our laboratory facilities out at Creve Coeur at our world headquarters.

Q. And as well, Exhibits 4-C and 4-M?

A. That's correct.

[170] Q. Those are all located here at the Monsanto headquarters in St. Louis?

A. Yes, they are.

Q. Now what effect, if any, can a minor difference in formulation have in terms of the performance of the pesticide?

A. It can have a substantial difference. For a change in emulsifier or a solvent, the so called inert ingredients even, if you shift those and you're applying the product post-emergent to the crop, there are some solvents that will substantially damage the crop itself. You get what we call solvent burn. And one has to look at that. If you change emulsifiers, the ones that cause it to mix well with water, and you did not check out the emulsifier to see if it would also handle well in fertilizer solutions, you

get what we call jelly built up in the fertilizer solution. It clogs the farmer's equipment, it won't spray. And in some cases you can actually get a material that can react with other pesticides if you are mixing them, and cause them to not be applied well.

So when we change a formulation we undertake a very thorough study over and above those toxicology requirements which are required by the registration group in EPA. We also have to look at it on a wide range of things, ranging from shelf life to efficacy.

[171] Q. Now at some point there is some effort given in connection with the manufacturing process; is that correct, sir?

A. Yes.

Q. Could you describe for the Court what work is done in general terms in that area?

A. Well, they take one of several different approaches. First of all, you're trying to manufacture in an economical way the highest purity product that you have. Our average assay on Lasso has gone up several percentage points since we first went in there. You're trying to modify the manufacturing process so that you reduce the amount of waste being discharged. In other words, less waste you discharge the better off everyone is. You're trying to modify the manufacturing process to achieve economic gain, a more inexpensive way of manufacturing. In some cases you're trying to eliminate an undesirable impurity that you may not want in there. All of these would be reasons to modify the manufacturing process; and that is an ongoing process. For every one of our products we never stop studying our manufacturing process.

Q. Now what kind of considerations do you have to have in that connection in terms of feed stocks, other environmental controls, those kinds of things that relate to how you develop the manufacturing process?

[172] A. Well, you must be assured of a source of raw materials for the manufacturing process. You must be assured of a continuing dependable economic supply of

those; and you must be sure that the manufacturing process itself must meet the specifications of other environmental laws.

Q. Now let me hand you what has been marked for identification purposes as plaintiff's Exhibit 4-K, and ask you to examine that and identify it for the Court, please.

A. This is a picture taken of one of our control climate rooms, growth chambers. There appears we're growing a series of plants under some fairly high light intensity. The purpose of these control climate rooms is to exactly control all environmental aspects, relative humidity, air temperature, air flow, various gas concentrations, soil temperatures, light intensity, so that we can find out with a reasonable degree of assurance and reproducibility, what impact the chemical is having on the plant under certain conditions; or conversely, to find out what impact the plant is having on the chemical. And these growth chambers are extremely expensive to maintain. They're under a great deal of automation, automatic controls, adjustment recorders and so forth.

Q. Do they relate in any way to your metabolism [173] studies?

A. These are one of the key components in determining the fate of chemicals in soils and in plants, which is a key part of the metabolism studies.

The COURT: Pardon me, artificial light is comparable to sunlight?

A. No, sir.

The COURT: I was just wondering about the possibility of photosynthesis?

A. Well, you're right. And most of the early works on growth chambers were not good work, because they did not design the proper lights that would give the equivalent of sunlight. And since that point in time they have gone back and you buy a specially designed bulb that gives you the quality of light you want. It's an art in terms of being able to design your—get the light intensity

you want and not get too much heat generated, and get the quality of light you want.

The COURT: Go ahead.

By Mr. HEINEMAN:

Q. Now in discussing generally the metabolism, residue and environmental chemistry aspect, let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 6, and ask you if you would examine that and identify it for the record, please.

A. This is a rather detailed, one-page sheet [174] showing what takes place from discovery to sales of a pesticide target, starting at the top, identifying the target. You might point out that although you identify Johnson grass as a target, for instance, you always ask yourself the question as the years go by, is it still a viable target. With Johnson grass the answer is yes. With some other weeds we say no. We will not screen against those weeds anymore, they are not commercially important. So the reason it's a dotted line, that's an open-ended assignment.

On synthesis, in the second one, obviously when we discover the chemical, the bar at the end of the solid line says we have discovered it. But synthesis also continues as you look for a better candidate. In the biological evaluation for patent application, once again you file for the patent with a certain amount of data, as I indicated on the earlier chart. But once again, you continue your biological evaluations even though you have filed for a patent application.

The research field plots show no bar and are open-ended because we continue research field plots with products until they're dropped from commercialization. There is never an end to putting our research field plots for any product that you sell.

Q. Let me ask you, tell the Court for the record [175] how this document came to be prepared and what it represents.

A. Well, this represents the various components, if you will, with the exception of the patent application. But

even the biological evaluation of the patent application, all of these are component parts of the registration package down through No. 10, that is submitted to EPA for label approval.

Q. And how was this document prepared?

A. This was done by working with the various people who have these responsibilities.

Q. And was it done——

The COURT: Well, now, just a minute. I'm drawing a red line under toxicology.

A. Yes, sir.

The COURT: Is it your testimony that everything above that line goes to EPA in connection with an application for registration?

A. Well, No. 6, the commercial decision, really is not data; but it's a checkpoint that is made. So you can scratch that. But everything, 2 through 10, with the exception of the commercialization decision, is a part of the registration package.

The COURT: Anything below that line?

A. Some part of the process chemistry, No. 13. [176] And of course we submit a label for EPA approval, No. 13. There's two 13's on there.

The COURT: Two 14's.

A. Yes, two 13's and 14's. Anyway, both 13's are submitted. In other words, we submit a label which EPA accepts or rejects or asks that we modify.

The COURT: Let me ask one question which I'm sure everybody will say is facetious. But due to the efforts of the manufacturers of herbicides, have these efforts ever made certain weeds an endangered species?

A. No, sir, not to my knowledge. I guess that's one of the bright spots that you can say about the field of herbicides. We used to think that we would eradicate some weeds; but as we have gotten smarter over the years we found out that weeds are going to be with us as long as we have agriculture.

The COURT: Go ahead.

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By Mr. HEINEMAN:

Q. Now is Exhibit 6 prepared under your direction, Dr. Carpenter?

A. Yes.

Q. And would you tell us across the top there it shows years. Now what——

A. Well, if you look—you really have under synthesis, you show that as actually having the compound made at minus the first year with zero year starting—going [177] in that last year before you reach the first biological evaluation. Anytime after that zero year that compound has looked promising enough that you're going to work with it. In other words, you have said this is a candidate for commercialization as opposed to item 6, which is your commercialization decision. That's when you really decided that you will commit all of the resources necessary, and that you have decided that is a commercial candidate or is a commercial product, until you've shown otherwise. Up until year three it's a candidate for commercialization; but you haven't committed the resources that are committed. If you will note after item 6, metabolism and environmental chemistry, residue and toxicology starts in earnest at that point in time.

Q. And those are the areas which you're preparing for the actual registration of a product?

A. That's correct.

Q. Now prior to that time the biological evaluation, the research field tests and the product development field tests, are the results of these tests also submitted to EPA?

A. Yes, they are.

Q. Now you touched briefly yesterday on the subject of metabolism. And the metabolism, would you explain for the record in general terms what the metabolism [178] tests accomplish?

A. In general, the metabolism tests are the beginning of those studies in terms of what we're trying to accomplish. That will show what happens to the chemical in

the environment, in water, what impact it will—how it's broken down in the plant, how it's broken down in the soils, and indeed, how it's broken down in the animals in the event that they ingest it. In other words, it's the fate of the chemical.

The COURT: Counsel, there's been no objection but I recall with some clarity his testimony yesterday. And I think this may be repetitious. I think he's going back over the same track on what happens; because he went into that in some detail yesterday.

Mr. HEINEMAN: All right, sir.

By Mr. HEINEMAN:

Q. Let me have you identify some of these photographs, Dr. Carpenter. First of all, would you look at what's been marked as plaintiff's Exhibit No. 4-E and identify that for the record, please?

A. In order to handle the massive amount of data in all phases of our toxicology, our synthesis, our screening, our metabolism, our residue, all of our programs, we now have put on a data system, a computer system if you will. And we now have extremely large sophisticated computer programs to enable us to handle recall, utilize [179] this massive amount of data generated by all aspects of the program on the chart we have discussed earlier. And this is the computer room, our central computer room for agriculture.

Q. This is just for the Ag Products Company?

A. That's right.

Q. Now let me hand you what's been marked for identification purposes as plaintiff's Exhibit 4-R and ask you to examine that and identify it for the Court, please.

A. This is another one of our scientists. In this case, this man is working on analytical methodology detections of minute amounts of material. He could be doing this as part of the residue group, he could be doing it as part of the metabolism group. But at any rate, this is extremely sensitive, complex work.

Q. Let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 4-A and ask you to examine that and identify it for the record, please.

A. Over under the lighted chamber to the left, in the left-hand part of the picture there is a soybean plant sitting there. And the instruments that are shown in the center part of the picture are hooked in by various techniques to record the gas exchanges of the soybean leaf in a very sensitive manner and determine such things as evolution of the radioactive pesticides, if we were to find [180] radioactive materials, or to measure photosynthesis, the impact of the chemical on photosynthesis or some other scientific aspect.

Q. And a little more detailed photograph which is marked for identification purposes as 4-G. If you would examine that and identify it for the record, please.

A. This is a closeup of the plant that was shown in the previous photograph in which you have the soybean plant, and we use only one leaf of the plant for our measuring purposes. And the rest of the soybean plant, the leaf remains attached to the soybean plant while we're carrying out these very sensitive measures. It's a rather unique tool.

Q. And what is in the chamber there to the left? Is that where the leaf is located?

A. The leaf is in the chamber itself and isolated completely in an independent atmosphere. All of this data must be used in submission to EPA for the metabolism requirements for registration.

Q. Let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 4-H, and ask you to examine that and identify it for the record, please.

A. We frequently work with radioisotopes or labeled materials. This represents one of the instruments [181] that we use in determining the various levels of radioactivity in the various fractions that we're measuring.

Q. And if you would, please, examine what has been marked as plaintiff's Exhibit 4-D and identify that for the record, please.

A. We're growing corn here in nutrient culture, probably these will go into our growth—control climate room, or growth chambers that will be used for either metabolism, residue or some purpose. And these—each pot is monitored by a number of devices to make sure concentration, salinity, oxidation and—oxygenization and all these other factors are—so that the plants are grown identical.

Q. To maintain an identical growth situation for each plant?

A. That's right, and reproducible from one experiment to another.

Q. Let me hand you what has been marked as Exhibit 4-P, and ask you to examine that and identify it for the Court, please.

A. This is a bank of chromatographs that we use to determine various fractions of the pesticide in the various fractions of the plant. In other words, this is part of the residue analysis. I might add that our [182] Director of Environmental Chemistry who also has responsibility for the residue work has pointed out to the new product committee meetings on occasion that the equipment used for analytical purposes by and large is getting outdated every three to five years. The methodology is changing so rapidly that the equipment that we're using has a certain level of efficiency, or a certain level of precision or detection. And these are rapidly being replaced by better equipment. And if you're going to have the up-to-date equipment, be at the leading edge of technology, then you must be continually updating your equipment, if you're going to have the best science and best equipment available.

Q. Let me hand you next what's been marked for identification as plaintiff's Exhibit 4-B and ask you to examine that and identify it for the Court, please.

A. This is a picture of a person working in our toxicology laboratories which we call our environmental health labs, where they're examining a slide of animal tissue from one of our toxicology studies, to determine the impact, if any, of the chemical on the animal.

Q. And if you would examine for me, please, Exhibit 4-F and describe that for the Court, please.

A. This is a battery of cages, in this case I believe those are white rats. We use rats as one of the [183] more frequent animals in toxicology, and particularly for the long-term chronic studies that go on for thirty months. As they test animals this is one of the batteries we use.

Q. And if you would examine, please, Exhibit 4-O and identify that for the Court, please.

A. This lady is preparing a tissue slide from one of the toxicology studies which would then be examined, if you will, by the person that we looked at earlier that was examining one of these slides. In a single rat study now we are up to, depending upon the type of study, between ten and twenty-five thousand slides per study when you conduct toxicology studies.

The COURT: In other words, what this lady here is doing is mounting the slides for later inspection?

A. Yes, sir, exactly.

By Mr. HEINEMAN:

Q. Let me hand you, if I may, Exhibit 4-I and have you examine that, and identify it for the Court, please.

A. This is another computer room. And this is where we're computerizing—putting our toxicology data in on the computer similar to that that we—that much larger room that handled all of our other data out at our research labs. And also it has an information storage and retrieval system whereby we can call up various toxicology studies and [184] information on various products.

Q. And is your environmental health laboratory located here at St. Louis as well?

A. Yes, it's not far from Barnes Hospital, in that area.

Q. Now, Dr. Carpenter, would you tell the Court briefly how does the EPA, to your knowledge, go about examining Monsanto's data for the purpose of granting or rejecting a registration?

Ms. MAYER: I object, your Honor. I don't think there's been any—the witness can speak to how EPA analyzes Monsanto's data.

The COURT: Well, if he knows he may testify. If he don't know he can say so.

A. The registration group in Monsanto that handles our petitions and submissions to EPA reported to me for several years. The registration manager, Dr. Serti, reports it directly to me. The correspondence that the registration group and our Washington office had both to and from EPA came across my desk. The visits that our people had with EPA were discussed by these people with me. To that end, when a petition is received——

Ms. MAYER: Your Honor, I think that he can certainly testify about Monsanto's experience. But I think the question was how does EPA handle what Monsanto——

[185] The COURT: Well, his answers are being restricted to how EPA handles their affairs with Monsanto.

A. Yes, sir.

Mr. HEINEMAN: That's the intent.

The COURT: And I wonder in passing—and this is certainly no inference pro or con on EPA—but I'm wondering if this litigation which started in early '79 has had any effect on the failure to register Machete?

A. No, sir.

The COURT: All right. Well, go ahead. I wanted to get that out of the way.

A. We got all sorts of arguments but that is not one of them.

The COURT: You may testify as to—and this may violate the hearsay rule—but you may testify as to what you observed from documentation received from your people and your Washington folks, together with their professional comments to you concerning that.

A. I might say that I have also called on EPA in the EPA registration group, including Mr. Taylor of EPA who is responsible for herbicide registrations in Monsanto products specifically. I have called on him in his office in EPA several times to discuss specific registration issues. I have called on Ed Johnson who heads up all—who heads up the Office of Pesticides for all of EPA. And I have called [186] on him in his office and had discussions with him.

Usually a petition for registration, or a new use for a registration is received by EPA and they have groups that handle various aspects of the petition. For instance, they would have those people that are assigned to look at the metabolism area, those people that would be assigned to look at the toxicology area, and so forth. So that the appropriate people or sections of EPA would look at the various sections, and they would review it and send it back to some central place with appropriate comments.

The COURT: Now supposen I come in with a me-too application. Who handles that? The same people or if you know? Well, wait a minute, you never filed a me-too, have you? I withdraw the question.

A. We haven't filed a me-too, nor has a me-too been granted for our products.

The COURT: All right. Go ahead.

By Mr. HEINEMAN:

Q. Well, then, Dr. Carpenter, does the EPA, to your knowledge, sir, examine and review the data that you submit on a new product when you submit it for registration?

A. Yes.

Q. All right. Do you have an opinion, sir, as to whether or not that data can be thoroughly evaluated by the EPA without necessity of public disclosure?

[187] A. Yes, it can be.

The COURT: He has an opinion, and the answer is yes.

By Mr. HEINEMAN:

Q. To your knowledge, sir, does EPA have any other sources available to it in terms of evaluation of data, other than public disclosure?

A. There are procedures that have involved our products called the RPAR process. And this stands for rebutable presumption. And this is when there is a currently registered product and some new data would come up that would cause EPA to have concern about that product; at that point in time the company must then go back and rebut the presumption that it should be cancelled or some change should be made. The EPA has a group of scientists called the Scientific Advisory Panel which consists of outside scientists who are experts in certain fields including toxicology, medicine, metabolism, physiology, what have you. And the data is presented to them both by EPA and by the company, or the owner of the registration. And the Scientific Advisory Panel reviews that data and makes recommendations to EPA for actions to be taken. The EPA may or may not choose to follow any or all of the recommendations of the advisory panel. there is a broader scientific advisory board for all of EPA, and they have various subsections for other issues.

[188] Q. In your opinion, sir, does the public disclosure called for by the 1978 amendments to FIFRA add anything to this decisionmaking process?

A. No, it does not.

Q. Do you have an opinion, sir, as to the ability of the public to understand and comprehend the data that Monsanto has submitted in support of the registration for example of Roundup?

* * * * *

A. The data contained on that cart over there [189] represents the data that has been submitted for Roundup. The data is extremely complex, and in fact, very few scientists could follow with any detail and interpret that data. The vast majority of the pubic, including me, cannot

follow some of that data. And I regard myself as very skilled in this.

* * * * *

[190] By Mr. HEINEMAN:

Q. Dr. Carpenter, does the label that Monsanto submits to the EPA for approval contain safety precautions for handling and use of the product?

A. Yes, it does.

Q. Does the data which is submitted in support of the registration in any way explain or make more clear to the user those safety precautions that are listed on the label?

A. No, they do not.

Q. Do you have an opinion, sir, as to whether or not there would be benefit to be derived from replicative studies in support of registration of the same chemicals?

A. There would be incremental benefits to be gained. We replicate our own efficacy data dozens of times to insure that we are writing the best label for consistency. Since manufacturing processes can vary as to how the active ingredient is made, that certain byproducts of the manufacturing process themselves can vary in terms of amount, the presence of them, the ratio of them, this [191] can affect the toxicology properties of the chemical and therefore could affect the type of warning that would be needed on the label. There are a number of ways that repetitive testing could be useful.

The COURT: Well, getting down to the bare bones—hand me that one little four-page document that somebody referred to yesterday. And I'm not going to mark it as an exhibit, but I just want to look at it. Yes, that's the one. This is the secret of secrets, is it?

Mr. HEINEMAN: Yes, sir.

The COURT: All right, Now the Court has in its hand the document—and I'm not going to mark it as an exhibit or—that's up to you folks. This document says volume 2 of 19, section A chemistry, section B use directions. This is that part that is not disclosable?

A. Yes, sir.

* * * * *

[199] By Mr. HEINEMAN:

Q. Dr. Carpenter, what is it [200] that is disclosed, sir, by—let's assume in connection with the Roundup data, the data that's been submitted to EPA in support of the Roundup registration, what is it in that data which the 1978 amendments to FIFRA contemplate being disclosed?

A. Well, the items that I checked off that were on the chart earlier, efficacy, metabolism, environmental impact, toxicology, in fact, once again, everything in the petition except the few pages of formulation and manufacturing process.

* * * * *

[201] By Mr. HEINEMAN:

Q. Now, Dr. Carpenter, previously you had reference to one book, a very thin book which was volume 2 of all of the data that was on the sled over here and was identified by you and a photograph of that data, which was Exhibit 7-A and B.

A. Yes, sir.

Q. Now in connection with that one book let me hand you what has been previously marked as plaintiff's Exhibit No. 39, and ask you to examine that and compare it with a portion of that book which you previously discussed.

[202] A. Yes. These are the procedures—or this is the formulation data which is to be held confidential and is excluded from consideration under 3(C) and 10(D), these two pages.

* * * * *

By Mr. HEINEMAN:

Q. Okay. Now Exhibit 39 is a Xerox copy of the first two pages of section A of volume 2 of 19 of the information to support the establishment of permanent tolerances and label registration for the use of Roundup as a preplant herbicide on corn, soybeans, wheat and other small grains, dated July 12, 1974; is that correct?

A. Yes, sir.

* * * * *

[216] By Mr. HEINEMAN:

Q. Dr. Carpenter, what is it that is contained in Exhibit 39?

A. It has the name of the chemical and then the structural formula of the chemical, a brief listing of the physical and chemical properties, and then the composition of the product itself which is to be sold to the public, and then a brief paragraph briefly describing how we make the active ingredient.

[217] Q. Is that the latter labeled manufacturing process?

A. Yes, it is.

Q. And what is contained on page 1 is what Monsanto refers to as the confidential formula?

A. Yes, it is.

* * * * *

[218] By Mr. HEINEMAN:

Q. Now, Dr. Carpenter, let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 14, and let me ask you to examine that and identify it for the Court.

A. This is a letter to Monsanto from the Environmental Protection Agency. They sent it our Washington office which—and then our Washington office refers it to the proper person within Monsanto. This is a request or a letter from EPA stating that they have received a freedom of information request from Ciba-Geigy Corporation asking for our data on—and they give a registration number 524-EUP-56. 524 stands for the Monsanto registration. Any product that EPA gives a label to Monsanto starts with the number 524. EUP stands for experimental use permit, indicating that it's used under section 5 of the Act. And it's just that experimental use. And there's certain things we have to do to comply [219] with that. And 56 just has a number of definitions. But 524-EUP-56 has to do with Roundup. That is an experimental use permit

for Roundup, one of the documents for Roundup that we have submitted to the Agency. And this says that EPA will determine if the document is entitled to confidential treatment.

* * * * *

[220] By Mr. HEINEMAN:

Now, Dr. Carpenter, let me hand you what has been marked for identification purposes as plaintiff's Exhibit No. 13 and ask you to examine that and indentify it for the record, please.

A. This is a pesticide catalog of a company called Aceto in which they list the various pesticides which they say that they will supply, they will sell to customers. And it is broken out.

The COURT: Well, they're a jobber I take it instead of a manufacturer; is that correct, or not?

A. Well, we refer to them quite frequently as one of the me-tooers. They buy their technical material from a wide range of sources including foreign manufacturers, and then offer it in competition. They are an example of the type of people that will come in for a request of use of your data to register their product. They carry—this company has no basic research in screening. I have never seen in my twenty something years in the pesticide field, I have seen no evidence of a techical effort of a toxicology [221] effort, of an environmental impact effort on the part of this organization. They merely are jobbers, is one way of expressing it.

By. Mr. HEINEMAN:

Q. I note, sir, that on the second page of that exhibit where they list herbicides, they list the Aceto brand name on the left and then the competitior's brand name on the right?

A. Yes, sir.

Q. Has Monsanto, to your knowledge, yet appeared in an Aceto pesticide catalog?

A. Yes. In the early years they did have either Ramrod or Lasso listed as one of the things offered for sale in the

U.S. And upon questioning by Monsanto they acknowledged they did not. And in this particular issue the Monsanto products were not listed.

Q. Were those products offered by Aceto in that catalog at a time when they were under patent in the United States?

A. Yes, they were.

Q. But, they have been omitted from the 1980 catalog?

A. They're not listed in this 1980 catalog.

* * * * *

[222]

CROSS-EXAMINATION

By Ms. MAYER:

* * * * *

A. I think what I said was that we apply for [223] patents for a substantially larger number of chemicals than we commercialize. However, we probably apply for only one out of ten to one out of a hundred of the chemicals that we made. In other woods, we do not apply for patents for every chemical we make, only for certain ones.

Q. But for chemicals that you have——

A. Applied for.

Q. [continuing]: —applied for a patent on, what is the number of years, if you can estimate, what is the number or years between application and issuance of the patent?

A. We have gotten chemicals in as short a time as a year. In some cases we have—it has taken six years.

Q. Okay. Fine. Now I'd like to focus on two chemicals, two herbicides that Monsanto has discovered and commercialized. The first one we focus on is Lasso. Is it true that Lasso was registered with the EPA in 1969?

A. It was registered for the first use in 1969. I think we actually got our first registration with USDA—EPA did not exist at that time—we got our first registration in December of '68, I believe, but it was for the '69 season.

Q. Fine. Is it true that Lasso was patented also in 1969?

A. No, it was patented later than that, I think [224] I mentioned that in my testimony. But I think we received our patent on that in 1972.

Q. So that you were able to sell Lasso for, let's say two years, approximately two years before actually receiving your patent?

A. That's correct.

Q. And then you had another seventeen years of patent protection after you received the patent?

A. Yes, we have seventeen years after we receive the patent.

Q. For a total of nineteen years after registration?

A. We received the patent—we had patent protection for seventeen years. We will have patent protection in the nineteenth year of our sales.

Q. Fine. Have you recovered all of your costs incurred in developing Lasso?

A. Yes.

Q. Do you know at what point you recovered all those costs?

A. Well——

Q. If you know.

A. The question is have we recovered all of our costs. We continue to apply additional costs to Lasso. If you look—if you are referring to the original [225] cost of registration and of the investment that was needed to get us to our first year of sales, we recovered those at approximately 1973 or '74. But since that time we have invested, in terms on plant, equipment, and other expense resources, we have continued to expand our plant and there are probably a significant part of our capital now for Lasso which have not been recovered as of yet.

Q. Okay. If I might, you had drawn a graph on one of these exhibits. I believe it was Exhibit No. 38?

A. Yes.

Q. Yes.

A. And if you are asking me have we recovered this——

Q. Yes.

A. Yes, we have recovered that.

Q. And was that done in '73 or '74?

A. Approximately '73 or '74.

Q. All right. Okay. Now concerning Roundup, was that registered with EPA in about 1976?

A. Our first crop use was registered in 1976 for use in crops. Our first commercial use involving an EPA registration was for non-crop use. And I believe that was in either late '74, but in time for 1975 sales.

Q. And when was Roundup patented?

A. It was '74, '75 to the best of my knowledge.

[226] Q. So it was within a year or two before receiving your first crop registration?

A. It was about the same time or a year plus or minus either way.

Q. And that patent will run into the 1990's; isn't that correct?

A. Seventeen in '75–'92.

Q. Okay. Now you testified that that is one of your most profitable herbicides; isn't that correct?

A. Yes.

Q. Have you recovered all of your costs on Roundup in that same meaning as——

A. In comparison to the same situation for Lasso in terms of initial cost pertaining to registration and initial sales, yes.

* * * * *

[240] Q. Going back to this plaintiff's Exhibit No. 5, did you take into account any tax consequences or depreciation or deductions when you were figuring your cost figures?

A. No, we looked at cost.

Q. So you did not?

A. Expenses.

Q. Okay. And you did not incorporate any tax advantages or tax consequences of your expenditures?

A. No, we did not.

Q. And it's a fact that generally your captial expenditures are depreciated on your income tax return; is that correct?

A. Yes.

Q. And your expenses are deducted on your income tax returns?

A. To the extent there's a profit, yes.

Q. Okay. Can you give me examples of what kind of expenses you would deduct?

A. All research expenditures or valid cost figures of doing business.

Q. How about salaries?

A. That's part of the research effort, yes.

[241] Q. What kind of things are capital expenditures that you would depreciate? Would all of this equipment that you have testified about and that we have seen in some of these pictures, would that kind of equipment be depreciated on your tax returns, if you know?

A. We use as a point of departure, as a general rule if it hasn't changed in the last year or two, a little less than a thousand dollars as to whether we expense an item and deduct the total amount as an expense of doing business, or whether we capitalize it. Now by and large most of these items of equipment that are in the photographs were far greater than a thousand dollars. And they would be capitalized, in other words written off over a number of years as opposed to being written off in a single year's expense.

Q. You are aware that under section 3(c)(1)(D) of of the act other companies don't have actual physical access to your data; is that correct?

A. Yes.

* * * * *

[250] Q. Okay. During your direct testimony I think you testified that one of the possible results of disclosure under section 10 is that a company could use your data in a foreign country to get a foreign registration. Was that your testimony?

A. Yes.

Q. Are you aware that under section 10 registration information is not disclosable to companies that do business in foreign countries?

A. The letter that we turned in in Exhibit 39—I beg your pardon—plaintiff's Exhibit No. 14, was a request for data from Ciba Geigy.

Q. Was that disclosed, was any information disclosed to Ciba Geigy?

A. If we had not acted on our own to prevent it it would have been disclosed. The Agency was prepared to give it to them if we had done it regardless of whether it was multinational or not.

Q. My question was, was any information disclosed as a result of the Ciba-Geigy request?

A. No.

• • • • •

[255] Q. In your direct testimony you also testified, I think, that there are about eight to ten companies in the United States with research and development capabilities that are on par with Monsanto's; do you recall that?

A. Yes.

Q. Can you name those companies for me? And let me combine two questions because I think it would be easier. And when you name them, can you indicate whether or not those companies operate in foreign countries?

A. All of the companies that I will name do operate in foreign countries, okay. Dow, du Pont, American Cyan, Stauffer, Union Carbide, Eli Lilly, Velsicol.

Q. I think that's seven. If you can't recall any others, that's fine.

A. Well, that's the flavor.

[256] Q. So all of these are multinational corporations?

A. Yes.

Q. And data may not be disclosed to them under the operation of section 10; isn't that correct?

A. According to the statute.

• • • • •

[263] A. Okay. In order to have a final end product you would have to start with the technical pesticide, which I referred to earlier. You would have to develop—if you were going to make—if you were going to—you, company X, were going to start with your own—make your own, and were not going to purchase it from outside this country and you were going to rely upon your own manufacturing sources, then you would have to obviously develop a manufacturing process. And that would give you the technical pesticides to work with. You then could take the technical pesticide and would from there, you would develop your own confidential [264] formulation.

Q. Fine.

A. Is that your?

Q. Yes, that's fine. And I think you testified that, depending upon the actual formulation that you arrived at, there can be a big difference in the final product. You can take an active ingredient and formulate it in different ways and your results may vary widely; isn't that correct?

A. Yes.

Q. So that the actual formulation is very important and can make a big difference in whether or not a chemical or—I'm sorry—a final end product, herbicide, will be marketable; isn't that correct?

A. That's correct.

Q. I think you also testified that the manufacturing processes are also very important in whether or not your herbicide makes it on the market; isn't that correct?

A. Yes.

Q. And that it's important that you get your factory going and that you figure out how you're going to comply with all other kinds of laws, including other environmental laws like the Clean Air Act and the Clean Water Act; isn't that correct?

[265] A. That's correct.

Q. And again, this information is not disclosable within the meaning of the statute; isn't that correct, under the terms of section 10?

A. That's correct.

Q. And, of course, a company would still have to come up with its own marketing strategy; determine, you know, what markets it was going to try to penetrate, how much advertising it was going to do, who it was going to try to target its sales to. A company would have to come up on all that on its own too; isn't that correct?

A. It would have to develop its own marketing procedures.

* * * * *

[273] Q. Isn't it a fact that at times Monsanto itself publishes procedures for and results of its various tests?

A. Yes.

Q. And that Monsanto sometimes publishes efficacy data, methodology data, analytical data and environmental data?

A. Run those by me again?

Q. Efficacy data, methodology data?

A. Yes.

Q. Analytical data?

A. Yes.

Q. Environmental data?

A. Yes.

* * * * *

[275] Q. Do you actually provide the data to users?

A. Usually. In fact, I can't think of an exception. We usually provide them with summaries of the data. The academic data, the one generated by the universities is not our property. That's the property of the university. And usually the extension people at the university. And usually the extension people at the university also present that data. But even there, although it's available usually the university people present summaries. But that data which has both our product and our competi-

tors product in the same test is not our data. And that's usually made public by the USDA and academic people.

* * * * *

[276] The COURT: And, of course, there's a certain amount of salesmanship in this business when you get out in the farmer's town. And I appreciate the question going to what information, data or whatever you want to call it is furnished voluntarily by Monsanto over and above, or in addition to what is on the label.

A. Your Honor, the point is that the data we choose to supply to the public, or to our customer, is that data that we choose to do on our own by way of all of the impact it will have on Monsanto, the need to know and so forth. And the publication of analytical data or environmental data, we see that it provides a number of useful purposes, things that we decided that represent—where the advantages outweigh the disadvantages, to build a scientific reputation of our own scientists, to encourage—[277] to get status for them. We also do it to demonstrate the effectiveness. Sometimes it's necessary in some of our foreign registrations where an article published in a competent scientific journal is useful to a foreign company over and above——

The COURT: Does your competition do about the same thing?

A. Yes, sir.

The COURT: Are you able to learn anything from what they do over and above labels as to what the product is?

A. We obtain a certain amount of information from doing that; and they—in turn we recognize we're giving up a certain amount of information. But once again, we have internally weighed the decision. Before we release such an article it has to be approved by our Director of Patents, our Director of Research, the Director of Development, and in some cases by our Managing Director. So that we are very deliberate and very methodical about how we decide to release the data.

The COURT: In other words, what you're telling me is you play those cards pretty close to your vest; is that right?

A. Yes, sir, very deliberately, very judiciously, if I may use the word.

• • • • •

[279] Q. I asked you a question about whether Monsanto was able to use the data that it submits to EPA in developing new tests in trying to figure out what new chemicals to pursue, you know, in future research. Now there is nothing in section 3(c)(1)(D) or section 10 which precludes Monsanto or interferes with Monsanto's use of that data?

A. That's correct.

• • • • •

[280] By Ms. MAYER:

Q. Okay. One other question I'd like to clear up is, just before we broke I was asking you whether most of the techniques that Monsanto uses in its toxicology studies and its residue studies are known. And I meant to say whether they're known to other companies, but I may have said whether they're known to Monsanto. Are these—let me just reask the question, whether—isn't it [281] a fact that most of the techniques that Monsanto uses for residue detection, for toxicity tests, for fish and wildlife tests are known to other companies in the field?

A. No.

• • • • •

[313] Q. Isn't it a fact that if Monsanto is the only company on the market selling a certain herbicide, that it may then essentially price its herbicide by what the market will bear?

A. Absolutely no. We do not have a single use of Roundup, or a single use of Lasso where we don't have two or more competitors. Even though it's not the same chemical we must price—first of all we like to price to value. You were asking me about how we determine price and what the market will bear. We like to get for our product what we think it's worth. But we're also faced

with a competitive situation. For instance, in Lasso and [314] soybeans, there's ten competitors out there that we must consider as to what our pricing situation is.

• • • • •

[326] Q. Since 1950 has Monsanto been committed to research and development of herbicides?

A. Yes.

Q. Since 1978 has Monsanto lessened that commitment to the research and development of herbicides?

A. No.

Q. Since 1978 has Monsanto submitted data to the Environmental Protection Agency in support of its registrations for its herbicides?

A. Yes, it has.

Q. So you continue to support data in spite of the fact that this statute is on the books?

A. We continue to submit it.

• • • • •

[338] By Ms. MAYER:

Q. Dr. Carpenter, before the break we were discussing the disclosure provisions of section 10 of FIFRA. Is it your primary concern with disclosure that through disclosure someone might be able to infer your confidential statement of formula and manufacturing processes from this information?

A. No.

Q. Okay. So you're not concerned with that?

A. Yes, I am concerned. You asked if that was my primary concern. I am concerned about it, but that is not my primary concern.

• • • • •

[350] Q. Okay. Fine. Is it fair to say that in order to determine whether a given pesticide is "safe for use" you would need to know all of this type of information?

A. Yes. When you refer to safe, you're referring to safe to the environment, safe to fish and wildlife, safe to humans, safe to the consumer, and so forth. And then all of the data together would be needed.

Q. Fine. Are you aware that union groups that represent workers in chemical companies and also groups of farmers and people—farmers who can be exposed to these pesticides are interested in this type of information?

[351] A. Yes.

Q. Isn't it a fact that scientists outside of Monsanto can evaluate this data?

A. Your question is are there scientists outside of Monsanto who have the capability of evaluating that data, then the answer is yes.

Q. Are you aware that union groups and environmental groups can employ scientists capable of evaluating this data?

A. They can, yes.

Q. Okay. And isn't it a fact that scientists at universities can evaluate this data?

A. Yes.

Q. As a scientist if you wanted to evaluate any of the studies performed by Monsanto on, let's say Roundup, and determine whether that study was scientifically valid, wouldn't you want to examine that study itself?

A. Am I doing this as——

Q. As a scientist?

A. Not as a person charged with doing it under the regulations?

Q. As a scientist?

A. As a scientist I would want to see the data.

* * * * *

[362] REDIRECT EXAMINATION

By Mr. HEINEMAN:

* * * * *

[363] Q. Dr. Carpenter, in response to questioning by the government you testified that the damages to Monsanto [364] were not quantifiable. I wonder if you would, for the record, say why they're not quantifiable?

A. Well, in addition to not being sure what data will eventually be released, the term—the commercial implications of either use or disclosure—we're talking about use in this case, I presume, or are we talking about disclosure?

Q. Well, disclosure was what I had in mind, primarily.

A. Well, there's no way of determining what might be the fate of that data in terms of once a person who is duly authorized to receive that, he's not a multinational, he could with that data, he could then decide to publish it in the Sierra Club news and/or distribute copies to many of his members. And perhaps as a Dow or a Du Pont man that's president of the local Sierra Club or a Ciba-Geigy man, perhaps he is a bonafide member of an environmental group, and a year later without any planning or forethought joins a multinational company or goes to work for Aceto Chemical Company. So that there's no way of telling what is going to be the fate of that data once it's disclosed. There's no way for the data to be, from a practical standpoint, being kept from the hands of those people that could utilize it in ways that we would not like to see it used. So it becomes impossible on disclosure [365] to determine what's going to happen.

Q. Is there any way to predict how many competitors of Monsanto, if any, would get access to it?

A. I have no way of knowing.

Q. And therefore, is there any way to predict what the market impact of such a disclosure would be?

A. No, there is not.

Q. Is there any way to predict what the impact of a use would be in terms of market penetration?

A. No. If under use of data, under section 3, if one competitor applies for our data and only goes for one market, or one crop, that has one impact. If it's Aceto, that's going to have one impact; but if Dow decides to go in with their massive resources, that's another impact. And if all of them think it's so interesting that we have fifty applying for it rather than one, or any number between one

and above, then it's impossible to predict the impact on the marketplace. And therefore, what had been originally from a Lasso standpoint a total Monsanto market.

Q. Is there any doubt in your mind that there would be an impact on the marketplace?

A. There's no doubt in my mind that there would be an impact, and the impact would be devastating.

Q. But you just can't put a number on it?

[366] A. I cannot put a number on it for those reasons.

Q. The Government inquired of you with respect to whether or not as a scientist you would want to see all of the data if someone wanted to register a substantially similar product to a Monsanto product?

A. Uh-huh.

Q. Would you tell the court why as a scientist you would want to see all the data?

A. Well, first of all, in the statement of formula, once again the statement of formula requires only that you list the inert ingredients. And certainly without any real analytical study of the components that are in the technical pesticide, with a very thorough analysis, in both—in the—both in the inert ingredients or the technical pesticide—well, not—the byproducts of the manufacturing process, if you manufacture something and you end up with ninety-four percent of the real pesticide and six percent of things that are not pesticide, that is your technical. That six percent can include dozens of chemicals, possibly. Now then when we do our toxicology studies we're doing something by the manufacturing process that we are using. So that when we test the technical pesticide for those four studies that were named earlier, the mouse chronic carcinogenic study, the rat chronic [367] carcinogenic study, the three generation study, and—let's see—and the reproduction study, teratology studies, we study the technical material. And by virtue of studying that technical material, whatever impurities we have in our product we're also testing because they're fed to the rat. A product made by a different manufacturing process

that could still be ninety-four percent active and still have six percent of other things in it, would not necessarily and probably would not have the same active increment—inert byproduct ingredients, things that we could not predict.

Now not only would this have impact on toxicology, but if you're starting out with a chemical that's—trying to make a chemical that's supposed to kill plants, and it indeed does, and the other six percent may or may not have some biological property, even though you're not claiming them as a pesticide, you're not claiming them as part of the pesticide, they're just listed as part of the six percent—they could have a deterimental effect on the performance of the product. They could have a deterimental effect on the crop safety. They might have a deterimental effect on the environment. You can say, well, gee, six percent doesn't do it and we don't have to worry about it. But by the same token when we find an impurity, as I indicated with roundup at less than one part per million, we [368] did substantial analytical studies, toxicology studies, environmental impact studies, and residue studies on that one incidental product, that compound that did occur in our Roundup technical. And certainly if we're looking at parts per million that's a far cry from six percent.

Q. What can be the impact upon Monsanto Company of a me-too product that does not have replicative testing done to identify this six percent byproduct?

A. When that me-too product is in the marketplace it is another form of—Lasso's scientific name is Alachlor. They have Alachlor 2 out there. When the farmer uses Alachlor, once he's bought it and put it on the ground, as far as he's concerned he has got Alachlor. A custom applicator might put it on for the farmer, and the custom applicator might in the course of his business be putting on both Lasso and Alachlor 2. If there is damage to any one of several things in terms of liability exposure, lack of control of weeds, damage to the crop, damage to the

applicator, environmental impact of toxicity damage, illegal residues in the crop, Monsanto can rest assured that it will be sucked into any liability case that might come about, and would suffer not only the impact of the liability but loss of its reputation.

Q. You were shown on cross-examination a document identified as pesticide analytical manual. What [369] sort of information is contained in that manual?

A. That provides information that enables the appropriate person with adequate facilities and skills to analyze in foods or feeds or elsewhere, for the presence of the pesticide and/or its metabolites.

Q. Is it current information?

A. It is adequate information in that it is useful for the purposes intended. But by and large, as I testified earlier, analytical procedures and equipment are rapidly being outdated every three to five years. It certainly would not be, in all probability, our latest technology. It would be technology that would be acceptable but would be outdated.

Q. Does the pesticide analytical manual which you examined today disclose the techniques and methodologies which Monsanto Company is regarding today as being proprietary and confidential?

A. No, it does not. We submitted that information voluntarily after we receive a registration for our product.

Q. That is the information for the analytical manual?

A. That's right.

Q. In terms of this publication issue and the things that are published, would you describe for the record how it is that Monsanto goes about deciding what [370] kind of publication to make, and when to publish it, and the extent to which you do make a publication.

A. Well, first of all, one determines if first on a scientific basis. For instance, the article dealing with glyphosate in soils, we wanted to publish this to get the results and the techniques even, out into the literature. There are a number of academic scientists who are interested in this

sort of thing who are doing work on that, and it was useful information but information that was something like three to four years old. So in determination of how we do this, as I mentioned earlier, our Director of Patents, our Director of Research, our Director of Development and in some cases our Company Counsel, review this from several standpoints, what risks or disadvantage do we suffer if any in doing this, what are the reasons for doing this, and what advantages accrue. And on that we make a basis of doing it. In passing, that which we publish in the referred journals is not the same report that we submit to EPA. It is still a condensation and represents less than one percent of the data that we have submitted to EPA.

Q. When you deal with an outside laboratory to prepare data for Monsanto to submit to the EPA, generally under what terms is that relationship conducted?

A. Well, there are two key terms. First of all they do it according to our specifications. And we approve [371] the specifications. But secondly, they sign a confidentiality agreement with us for treatment of the data.

* * * * *

[374] DEFENDANT'S CASE

* * * * *

HERBERT HARRISON was called as a witness, and being first duly sworn to tell the truth, the whole truth and nothing but the truth, testified as follows:

* * * * *

[467] By Ms. MULKEY:

Q. Okay. Mr. Harrison, based on your experience in the registration of pesticides, would you describe for us the changes over the years in the amount and type of data that have been submitted to the agency by pesticide registrants?

A. Yes. Your Honor, as you may well know, in 1947 the first FIFRA was promulgated, put into effect. And since

that time a lot of changes have taken place in both understanding of pesticides and their problems and the Act itself.

Originally the Act, as I understand it, was promulgated more for efficacy then for anything else. Farmers wanted to make sure that the products worked. So that the early submissions were heavy enough in efficacy and light in health related data. As time went on it wasn't too long after that I guess until Rachel Carson wrote her [468] book on Silent Spring. So the Act changed from time to time, changed rather significantly in '64 to ask for more data of a public health type or environmental type. In '72 it was increased significantly. But between '64 and '72 there were more and more pieces of data required by the agency.

I looked at the Monsanto submission of data in what we call our level 2 catalog. The oldest volume of data that I show for Monsanto in that catalog was submitted in 1948. And there were a couple of volumes submitted in 1950, and then they started to grow from that time. But if you go from the first submission in '48 to when the interim policy statements were issued in '73, there was essentially between one and a half to two volumes submitted per month. If you look at the data submitted between '73, November of '73 and October of '78 when the law again was changed at that point and the new provisions put into effect, then Monsanto submitted on the average of six point five volumes per month. So we go from one up to six and a half. And then from that time up until this last July which is the last report we have from that particular catalog, they submit roughly twelve volumes of data per month. So you go from one, essentially one and a half up to six and a half up to twelve.

So as you can see, the data requirements have [469] significantly increased; and particularly increased when you understand, your Honor, that those early data were in heavy part efficacy data. They were no longer from '78 requiring efficacy data, so that's very little. So we shifted

from efficacy data to public health and environmental data very heavily.

* * * * *

[474] By Ms. MULKEY:

Q. Do you understand, Mr. Harrison, my question is designed to solicit from you a [475] description of the practice with respect to me-toos?

A. Yes. The way registration process was accomplished prior to my time as becoming the branch chief of the ecological registration branch, was that again a program specialist, which I was one, would work with a particular discipline such as the fungicide group, rodenticide group, and so on. We would received applications for any fungicide or rodenticide in the case in which I was involved, and if there are other people doing the herbicides—and of course at one point I did herbicides for a period of time—and we would make sure that the reviewers who needed to look at the label and the application would look at those and make whatever statement they had to make about the label and application and so forth. Whether they needed data, whether they needed more data, whether they needed data at all, whether they needed to have the label changed to take care of use of the product or whatever. So in a graphic way, your Honor, what would happen is that I would take from my office a registration file and give it to one of the reviewers who would at that point look upon information he had at his disposal, which was ususally a catalog of sorts. It would either be kept in a notebook or in a file catalog or what have you, just a card catalog. And he would look to see the information contained on that card as to what had previously been registered by the agency [476] for that active ingredient. He would look at the uses that had been registered. He would look at the percentages of the active ingredients in those products that had been registered, and would make the determination whether the me-too in fact was using the same percentage, had the same usage. And if so,

would simply say he was happy with what he had seen, he needed no further information, and pass it along.

That would happen with the safety people. That would happen with the efficacy people, with the environmental people and so forth, the chemists. And that's the way we manage to get so many applications done very quickly. Again, when I first came on with USDA, we did about fifty to seventy applications a day. That is, we had the reviews done, we wrote the letters, proofed the letters and mailed them out and so forth. And that particular aspect has probably fallen considerably over the years because of the more complicated processes that we now go through. But even before I had arrived I think there were between maybe sixty and a hundred per day. Because they were moving things through very, very quickly without looking at much information.

So that the processes that took place at this particular time require very little data review on the part of our reviewers. They just use the card catalog they [477] had. And in fact, at that time, USDA was putting out a document called the EPA compendium of registered uses where they would have in this particular compendium a listing of the chemicals, the various crops we had registered, the dosage rates, the preharvest interval, various limitations for the product use and so forth. And quite often our reviewers would use that particular document to review whether or not this was consistent with previously registered product. And very seldom did we look at data. Only where there was a new use or new chemical involved did we go back and look at efficacy data or chemistry data or toxicology data and so forth.

Q. Let me posit a hypothetical.

A. Yes.

Q. Let us suppose that USDA had previously registered an active ingredient for a product that Monsanto got a label on. And that another company submitted a registration to the agency for a chemical which contained that active ingredient. And let us suppose that their submittal

contained the following information: A label which looked exactly like Monsanto's label except that they changed the name of the company and the trademark of the product; a confidential statement of formula; and a request that the new label be approved. Would you describe the manner in which you would have handled such an [478] application?

Mr. HEINEMAN: Your Honor, may I object to the form of the hypothetical question in terms of time?

The COURT: Well, of course, the Congressional Rules of Evidence has pretty well ruled against your position. You may cross-examine. Go ahead. Overruled.

By Ms. MULKEY:

Q. I think it would be helpful perhaps if we established this as—let's pick the year 1968.

A. To the best of my ability to recall, what would happen is, the application would come to my office and I would determine which ones of the reviewers, if not all, would have to look at this particular application. And I would carry it to those reviewers for their review. Now the reviewers would, in this particular hypothetical example, would have originally registered the Monsanto product. And in that registration process they would have captured the information about the use directions, about the dosage rates and so forth. The safety people would have gotten off the information about what the toxicity categories were that would show on the label, such as whether it was dangerous or less dangerous or what have you. And the fish and wildlife people would have captured the kind of information about what kinds of labeling would have to appear for the fish and wildlife precautions on the label. [479] And when the second or subsequent application would come in, the me-too, they would go through their file until they came to that particular item, and see if the percentages were the same, uses were the same. And if the label essentially carried those same precautions, use directions and so forth, they would simply give it an okay and send it forward. And that

would go through the whole process in that manner and then be returned to myself. I would write the letter indicating that it could be registered and would immediately proceed to register it from that point.

Q. Okay. Would you—do you have in mind my hypothetical?

A. Yes.

Q. Would you take the same hypothetical except let's assume that the second application, the other company did not include a confidential statement of formula. How would you handle that kind of application?

A. We would obviously go back and ask the me-too applicant submitter, or the applicant to submit a statement of confidential formula. Now quite often what happened in those days was that they were buying a product from some other company, they'd be getting it off the shelf and buying it from Monsanto. But at that time they would have to go back to Monsanto and ask Monsanto to submit in their behalf their confidential formula for the product that they may be [480] buying off the shelf rather than going and buying it directly from Monsanto. Or if they bought it directly from Monsanto, Monsanto would have to support that company's registration basically with the confidential statement of formula so that we could know what was in the original product. And then we would have to know from the me-too if it was simply all of Monsanto's product or he was adding some carriers or what have you. But of course if the percentages were the same it probably simply would be are repackaging of Monsanto's product.

Q. Okay. Now so that I'm absolutely—so that we're absolutely clear on what you've just described, would you require that the me-tooer secure any permissions from Monsanto or anyone else, so long as the me-too's application package did include a confidential statement of formula?

A. Yes. Again, you see in order to make a determination on the appropriateness of the application we would

have to know what was in the product. Now in the case of this me-tooer, if he was using a Monsanto product—let's say it was a fifty percent emulsifiable concentrate, which meant that the active ingredient was at the level of fifty percent of the total product that they were buying from Monsanto—the purchaser, that is the me-too manufacturer, would not know what the other fifty percent was because that's inert ingredients and kept [481] confidential. So he would have to go to Monsanto and ask Monsanto to give him permission for the agency to either look in Monsanto's files for the original confidential formula, or in many cases would have Monsanto send that formula to us saying you can use this formula to support our registration. So that at that point we would know totally what was in the me-too formula. We would know what Monsanto had first put into their formula and then subsequently what the me-tooer had put or added to the Monsanto formula to make their product.

Q. And keeping in mind my hypothetical, did you in conducting your responsibilities at that time require the me-too applicant to secure any permissions from Monsanto in connection with anything other than the confidential statement of formula?

A. No, we did not.

Q. When you first went to USDA, that was when, in 1967?

A. June of 1967, I believe.

Q. Were you trained by other persons who were already performing the kinds of responsibilities that you came to perform?

A. Yes. The manner that the program—I think most everyone that came to the division, in particularly the program specialist was a type of apprenticeship that we [482] would work with people who were already performing those particular duties, and they would obviously give us some basic instructions. They gave us the law and regulations and a number of other items that we would look through. And then we would work directly with those

people reviewing and seeing that the product got reviewed by other people. And eventually we would be given these items to do ourselves. And then they would be screened and reviewed after we had finished to make sure that we had done what we should do and something hadn't been left out. There was a lot of verbal instructions in that situation. And that's basically the way we were trained.

Q. All right. During the period in which you were trained to perform these responsibilites, were you taught to perform them in the manner you have just described to this court?

A. That is the case.

Q. And I understand that you worked in at least two of the subject matter review sections, if you will, the fungicide-rodenticide section and the herbicide section?

A. That's correct.

Q. And in both you worked—do I understand you to say you worked in both of those sections prior to your being assigned to the ecological investigations branch?

[483] A. Yes. I worked—my first job on my own, so to speak in the Agency, was to work with the herbicide group. And I worked there something less than a year. Then I was switched over and worked with the fungicide-rodenticide group for somewhat longer prior to being assigned to the ecological investigations branch.

Q. All right. Did you perform your duties in the manner in which you just described when you were assigned to both of those two subject matter groups?

A. That is correct.

Q. And did other persons assigned to those two subject matter groups and positions similar to yours also perform their duties in that manner?

A. Yes. Some of those people that actually performed those kinds of duties were the people that helped train me.

Q. And in the course of your evaluating registration applications in the manner in which you have just de-

scribed, did the patent status of the previously registered chemical make a difference in the manner in which you performed your duties?

A. No, it didn't make any difference. As I think I testified earlier, that at least some of the things that we were told not to become involved with was the patent status of products and what the seller may want to sell them [484] for. I can recall as an example an instance where I saw a five-pound bag of fertilizer with a pesticide in it that they wanted to sell for thirty-five dollars. And I was shocked at that. And the people that I was working with said that it wasn't any of my business.

Q. After you were in the ecological investigations branch did you return to responsibilities for shepherding applications for registration through the Agency?

A. I'm sorry, I missed that question. Would you restate it?

Q. After you were working in the ecological investigations branch did you return to responsibilities for shepherding applications through the Agency?

A. Yes, I did, only not so—so specifically. I became branch chief of the newly formed at that time insecticide and rodenticide branch. So I was the chief. I got involved to some extent, but not to the nitty gritty as I had been in the earlier situation.

Q. And when did you shift to that responsibility from the ecological investigations branch?

A. September of 1971.

Q. Now after you were back in a review branch, were applications for registration handled in the manner that you described when you were describing your performance of your duties during the period 1967 to 1970 or so? [485] A. They were quite similar.

Mr. HEINEMAN. Your Honor, may I object to the question as calling for sheer speculation on the part of this witness. I don't think any foundation has been laid for him——

The COURT. Well, in view of the witness' previous statement concerning the possibility of advising an industrial client, I'm going to overrule the objection. You may answer.

A. Yes. The same review methods were used to have me-too products reviewed as it occurred between '67 and at the time I went to the Ecological Effects Branch, or Investigation Branch. And that was that the program specialist did carry these items to the various reviewers. And they did use their books and the USDA compendium and what have you to generally review the label, review the application without looking at data to make their determination; and on many occasions did personally go to these people and have this done as branch chief, particularly when there seem to be some kind of a problem that did come up.

* * * * *

[493] By Ms. MULKEY:

Q. Mr. HARRISON. I'll show you what has been marked for identification as defendant's exhibit P and I would like in an effort to try to expedite matters to also distribute what's been marked for identification as defendant's exhibits Q, R, S and T at the same time. Mr. Harrison, did you direct that a search be undertaken of Agency files in connection with documentation relating to the Agency's practice regarding me-too registrations in the period prior to the effectiveness of the 1972 amendments to FIFRA?

A. Yes, I did.

Q. Could you describe the nature of the search [494] that you directed be undertaken?

A. Yes. We asked the personnel within the Agency who were here at that time, during that time or may have files that were carried over from that time, to look to see if they could find any documentation that any letters that have been written in regards to patents or use of data or what have you, and in that relationship these particular documents were uncovered, one from Mr.

Alford, the exhibit P, and I believe Q, R, S and T, all were found in Mr. Adamczyk's files. In fact, I think Mr. Alford—Mr. Alford's letter actually was written and then signed by Mr. Alford. So they all showed up in Mr. Adamczyk's files. Mr. Adamczyk is a person that keeps most everything that he writes, and that's why it showed up. I personally do not keep files this long and therefore I didn't have any, if, in fact, I had ever written any such file letters in my tenure in that particular position between '67 and '70.

Q. Did the search of Agency files extend to individual registration jackets?

A. No, they did not. That would have been too laborious and time consuming.

Q. Okay. Now I'd like to direct your attention to what's been marked as defendant's exhibit P.

A. Yes.

Q. And in particular to the last line of the second [495] paragraph: If adequate data is on hand for a formulation further data is not needed.

A. Yes.

Q. Have you examined this letter?

A. Yes, I have.

Q. And is the statement contained in that sentence consistent with your understanding of the manner in which the Agency conducted evaluations of registrations?

A. Yes, it's totally consistent.

Q. I'd like to direct your attention to defendants' exhibit Q, and in particular to the second sentence of the last paragraph which states: If it is a pesticide that is well known and for which this division has toxicological and efficacy data on hand, such data would not be required to be submitted?

A. Yes, I see that and it is consistent with the policy which was in existence at that time.

Q. Are you aware of any special significance that the phrase: "If it is a pesticide that is well known" might

have and in connection with the conduct of registration applications at that time?

A. Well, obviously if it's a pesticide that we didn't know about, then they would have to submit the data. This is, if it were a new active ingredient this company was going to be submitting.

[496] Q. Did it have any other special significance that you know of?

A. Not that I can think of.

Q. Have you examined the contents of the letter in defendant's exhibit R?

A. Yes, I have.

Q. Do you understand it to be consistent with the practice as you understood it at that time?

A. Yes, I do.

Q. I'd like to turn your attention to the first sentence of that letter: This is in reference to our recent telephone conference regarding compounds whose patents have expired.

A. Yes.

Q. From your experience during this time does anything in that statement have significance with regard to the practice of the Agency regarding consideration of this type of application?

A. No, it's essentially the same.

Q. Turning your attention to defendant's exhibit S and ask you if you have examined that letter.

A. Yes, I have.

Q. And do you understand the contents of that letter to be consistent with the practice as you understood it?

[497] A. That's true.

Q. And to defendant's exhibit T and ask you if you have examined that letter?

A. Yes, I have.

Q. And do you understand it to be consistent with the practice as you have described it?

A. Yes, that's true.

* * * * *

[507] By Ms. MULKEY:

Q. Mr. Harrison, in your opinion does the material relating to toxicity and toxicology of a pesticide contained on a pesticide label, provide the entire scope of general information which an individual might be interested in regarding the toxicity of that chemical if the individual was to be dealing with the chemical?

* * * * *

A. All right, sir. The label basically talks about the acute toxicology of a product and its warnings that relate to that particular item. It does not say anything about the long-term problems that may exist from the use of the product such as whether it may cause cancer or be triogenic or mutagenic or what have you. However, there is a company who now has made application and has requested that we place on their label a statement that this [508] product has shown to cause cancer in animals. And as far as I can recall, sir, that may be the first time that has happened. But generally it does not talk about long-term problems that may or may not occur with that product.

By Ms. MULKEY:

Q. Mr. Harrison, if an individual wished to know the nature of the hazard to fish and wildlife in connection with a pesticide, could he derive that from reading the label?

A. Again, to a certain extent. The label doesn't necessarily tell the applicant what all the problems may be with that product. They will simply say, do not do this or that. Like for instance, do not place this product in water. It doesn't say particularly what all organisms may be affected if you do so. It just simply says don't do that. Because there are problems which really aren't particularly referred to in any extent on the label, so it's simply a direction of how not to use it and so forth.

Q. And with regard to other environmental hazards, does the label describe the nature of the hazards?

A. Generally not. It's just indicating that you shouldn't breathe the product or you shouldn't get it on your skin; or again, with fish and wildlife let's say you shouldn't apply to streams because fish may be killed. But of course there are other things that may be killed, that would occur in a stream too. But it's of a general [509] nature one that the average user, if he follows the directions and the precautions and uses it properly, then there would not be a hazard to the person or the environment involved.

* * * * *

CROSS-EXAMINATION

By Mr. HEINEMAN:

Q. Mr. Harrison, in connection with the exhibits DD and EE which you had reference to which were these Aceto registrations on Propachlor——

[510] A. Yes, sir.

Q. [continuing]: —issued on October 4th, 1971, and July 17th, 1972, was Monsanto Company ever advised that those registrations occurred?

A. There was no indication in the record that that happened, as far as I know, unless—let me see—no, I guess there's no record like that, that I can recall in the file. I have no personal knowledge if they were done outside of that.

Q. And at that time there was no provision for any publication of that information, was there?

A. That is correct.

Q. So that as I understand it, Aceto came in and wanted to get a registration on Monsanto's product; they were given that registration and Monsanto Company was never told about it at all?

A. That is correct, as far as I'm able to testify, except as the letter states that was written back when requested by Monsanto to Dr. Early, I believe it was, in 1973, I guess that was the time.

* * * * *

[517] By Mr. HEINEMAN:

Q. With respect to a product upon which Monsanto had been the data submitter on a new chemical——

A. All right.

Q. [continuing]: —prior to this Aceto registration on Propachlor on 1972, was there ever an occasion when a me-too was registered on a Monsanto product?

A. I just don't know.

[551]

* * * * *

Q. It certainly may not. Let me pose this possibility. Let's say that this arbitration thing drags on for five or six years and the me-tooer has been selling since he got the registration. And the arbitration award comes down and it's too much money, he doesn't want to pay it. What does he have to do?

Ms. MULKEY. Objection. Counsel is arguing with the witness.

The COURT. On the contrary. He's asking a question. Go ahead.

A. The law as I read it, not being a lawyer, but the law as I read it would indicate that the Agency would then at that time cancel the registration for the me-too product.

By Mr. HEINEMAN:

Q. Or he could just withdraw it, couldn't he?

A. That's another option.

The COURT. Supposing he took bankruptcy, what happens?

A. I guess he would be broke, your Honor.

The COURT. I know.

A. I suppose that's very possible.

[552] The COURT. Go ahead.

By Mr. HEINEMAN:

Q. So, he can stop selling, he would have to stop selling if you withdrew his registration, right?

A. Legally he would have to stop selling, that's right. Yes, sir.

Q. But he might continue to sell illegally?

A. People do that all the time.

Q. So then let's assume that he obeys the law and he stops. So in the meantime he has been selling Hungarian Glyphosate and making what I'm sure he hopes is a profit on it, and competing with Monsanto and perhaps taking their market away. And then when he finds out the price is too high he quits and he pays nothing. Is that the way the statute works?

A. My reading of the statute would indicate that that is the case.

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[560] RAYMOND LANDOLT was called as a witness, and being first duly sworn to tell the truth, the whole truth and nothing but the truth, testified as follows:

[561]

DIRECT EXAMINATION

By Mr. McLAUGHLIN:

• • • • •

Q. And you are currently employed in the office of pesticide programs at the Environmental Protection Agency; is that correct?

A. Yes, I am.

Q. And is it correct that you joined the United States Department of Agriculture in 1966?

A. Yes.

Q. And could you trace your Federal service from 1966 to the present time?

A. In March of 1966 I started to work in the Safety Evaluation Staff of the Registration Division of USDA. I was essentially in this position through the period of transition from the USDA to EPA until about 1972, June of 1972 when I was selected from a group of scientists within the organization to do an indepth review on twenty [562] chemicals that were concerned–of concern to the agency.

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[564] By Mr. McLAUGHLIN:

Q. Did Dr. Hays ever become deeply involved in the day-to-day activity at USDA?

A. Dr. Hays in his position of wearing two hats, one of division director and the other as branch chief of the Safety Evaluation Division, was a person that took great interest in our activity. Initially we had weekly meetings in the Safety Evaluation Staff to discuss problems. And then inasmuch as the workload was bearing on us, the frequency of these meetings diminished over a period of time.

Q. Did you ever explain to Dr. Hays the way you carried out your activities?

A. No, I did not.

Q. Did Dr. Hays ever give you detailed instructions on how to carry out your activities?

A. No, we did not, neither written nor verbal.

Q. Are you familiar with Mr. Greg Rohwer?

A. Yes. Mr. Rohwer took over as acting director following Dr. Hays.

Q. And did you ever explain to Mr. Rohwer the way you carried out your day-to-day activities?

A. No, I did not.

Q. And did he ever give you detailed instructions on how to carry out your day-to-day activities?

A. No, I saw very little of Mr. Rohwer.

[565] Q. Okay. And are you familiar with Cipriano Cueto, Dr. Cipriano Cueto?

A. Yes, I am. He was the branch chief of the Safety Evaluation Staff.

Q. And again did you ever explain to Dr. Cueto the manner in which you carried out your day-to-day activities?

A. My association with Dr. Cueto was one that would arise when we had problems in our specific sections for which we were doing our reviews.

Q. Okay. Would it be fair to say that you only went to Dr. Cueto when you did have problems?

A. We would seek his advice in requesting data for registration, or in interpreting the data that we had to review.

Q. Okay. You said you were a toxicology labeling data reviewer?

A. Yes.

Q. Could you go into a little bit more detail as to what that job involves?

A. The job involved obtaining an application for registration from one of the registration specialists, and inspecting the label and the contents of the application for completeness before I would start to make my evaluation of the label.

[566] Q. And what was the purpose of your evaluation?

A. The purpose of the evaluation was to determine whether precautionary labeling on the label was adequate for protection of the public; whether the first-aid antidote statement appeared and was adequate; whether the label contained safety claims that may lead to misuse of the product; and where a few use limitations that were pertinent to our evaluation as a safety reviewer.

* * * * *

[569] A. This is a copy of interpretation 18 published March 9th, 1962, in the Federal Register. It is somewhat—the only difference that I recognize in it is in its physical form, in other words, paper rather than in book from that I used.

Q. In other words, you used another printing of interpretation 18 in your day-to-day work; is that correct?

A. Yes, I did.

Q. And this is a version which was published in the Federal Register for public disclosure of interpretation 18?

A. My version?

Q. No, the version which you have?

A. Yes. This appears in all respects like the one that I was using.

Q. Okay. Could you tell me what was interpretation 18?

A. Interpretation 18 is comprised of a number of chemicals that have the most frequent uses that we were concerned with in the registration of pesticides.

Q. And what sort of information did it give?

A. There is—for each one of the chemicals that is listed in here there are break points given for the categories of toxicity that distinguish the different hazards involved from exposure to the pesticide, along with [570] precautionary labeling and first-aid statement.

Q. Okay. You used the term break point. What do you mean by that?

A. That for the particular concentration of the chemical involved is identified with a degree of severity. In other words, the break point, let's say parathion with—formulated as a dust, two percent and below carry the label warning; whereas two percent and above would be labeled with danger, poison, skull and cross bones.

Q. Okay. You mentioned also that you were introduced to another tool in your training called the label file; is that correct?

A. Yes.

Q. Okay. I'd like to show you defendant's Exhibit W. And are you familiar with this exhibit?

A. Exhibit W is copies of my card file that I have accumulated over the years.

Q. Okay. And what sort of information did you—was in this card file?

A. The card file consists of the chemical name of the pesticide identified on each card, along with physical and chemical characteristics of the chemical. There is precautionary labeling, and also identified are the company that has registered the chemical, the concentration of the chemical involved in the formulation, and again the [571] precautionary labeling and the toxicity data that was available on that particular formulation.

Q. Okay. I'd like to direct your attention to page 35 of defendant's Exhibit W. You will note on that page some

material has been blacked out. Could you explain why that material was blacked out?

A. Yes. It was blacked out because I was not certain of the source of the material.

Q. And what do you mean by you were not certain of the source of the material?

A. Oh, I see, okay. It's from a company other than Monsanto.

Q. And how did you select these; how were these cards selected to be included in this exhibit?

A. I went through my card file and pulled out all Monsanto cards.

Q. So, all of the cards in this file were taken from chemicals which had been registered by Monsanto?

A. Yes.

Q. And there is some data on your cards concerning—which could have been submitted by a company other than Monsanto; is that correct?

A. Yes.

Mr. HEINEMAN: Well, your Honor, let me object to that. I think he's speculating. I think he said [572] he couldn't tell for sure who it came from.

The COURT: Well, if he can say it did or didn't he may do so. If he can't say I think he can make a general allegation the part that came from here and part came from there if he knows.

A. If I may, I would turn to page 20. There is a case that I'm really not certain as to which company generated the data. Because there is Lever Brothers at the top and Monsanto at the bottom. And so either one of the companies could have generated it.

By Mr. MCLAUGHLIN:

Q. Would it be fair to say that from the face of this card you couldn't tell which data was supplied by which company on that——

A. No, I could not.

Q. [continuing]: —particular registration? Where did you get the information to put on your cards or that is on these cards?

A. Well, I started out with copying the cards of the fellow that was to train me. And then when I had a problem I would go to the other reviewers for information on their card. And knowing full well that I had to operate efficiently at this job I had to accumulate a file that was readily available to me on my desk. The—so the source of information—that source of information was within my group and then as I reviewed each registration that came [573] through that had a bit of data in it I would either make a new card or add that data to the existing card. All of this was to supplement 18, to assist me in my reviews.

The COURT: Let's take ten minutes.

[Whereupon, a ten-minute recess was taken, after which time the following proceedings were had:]

By Mr. MCLAUGHLIN:

Q. Mr. Landolt, before the recess we were talking about your training, and you explained the interpretation of 18 and the label file you established. I'd like to ask you a couple of more questions about that period. During your training were you ever instructed—when you were putting together your label file were you ever instructed not to put any data on your label file?

A. No. My data file is my working document to review labels.

Q. And where would you draw the information on that file from?

A. The data that went on my card or label file came from the registration jackets as I would review them, and came from other reviewers, came from the tox file that was available to me, and from the literature.

Q. Okay. And it would then both contain public information and information which was submitted with an application?

A. Yes, it would.

[574] Q. Okay. Were you told at any time there were any restrictions on your consideration of this information in reviewing an application?

A. No, I didn't receive any instruction.

• • • • •

[575] Q. Okay. I'd like to ask you some specific questions about how you performed your review of applications for registration. I believe you testified already that the purpose of your review was to determine the adequacy of the label in presenting the toxicology information which the Agency required to be on the label at the time. Could you tell the Court how you determined the adequacy of the [576] label?

A. Would you like the review process that I went through?

Q. Yes, please.

A. All right. Well, I received the jacket or the registration application, I read the reviewer's comments that had been written prior to my review. I went through the registration application jacket and reviewed the past history of the application. I looked at the confidential formula to see what the inerts and active ingredients consisted of. I read the corresponding letter from the registrant so that I would know what action was being requested. And then my next step would be to draw on the information that I had in interpretation 18, and see if the chemical in question was listed in interpretation 18.

Q. And if it was listed in interpretation 18, then what did you do?

A. If it was listed in interpretation 18 I just compared the percentage break points, the labeling; and if it was satisfactory I would approve it and send it on its way.

Q. Okay. And you would do that for all registrants?

A. For all registrants.

Q. Or all applicants I should have said?

[577] A. Yes.

Q. Okay. If it was not listed in interpretation 18?

A. Then I would turn to my card file and look up this particular chemical and see just what kind of information I had available to me.

Q. And what would you do with the information on your card file?

A. There too I would—it's essentially the same process that I went through with interpretation 18, was to compare the labeling, the percentages of the active ingredients. And also my card file would give me additional information on any other—information on the toxicity of it that I should be aware of.

Q. And when you used your card file did you consider all information on that card file for all applicants?

A. I would consider the information pertinent to the registration that I was reviewing.

Q. And by saying pertinent to the registration you were reviewing, what do you mean by that?

A. The percentage of active ingredients, and determine whether the precautionary labeling was consistent with what I had on my card file.

Q. So the curcial factor in whether the information on the card file would be applicable was the identify [578] of the active ingredient; is that correct?

A. Yes. Each one of my cards was identified with the active ingredient.

Q. And you were concerned with the active ingredient regardless of the identity of the source of the applicant; is that correct?

A. That's correct. And also in my reivew I was equally concerned about the inert ingredients, because they too can be toxic.

Q. And what would you do if you couldn't find any information in your label file regarding that particular active ingredient?

A. I would see what the other reviewers had in their files and then go to the tox files to see what was in the toxicology or the Safety Evaluation Branch files.

Q. Okay. Going back to the first step, seeing what the other reviewers had in their files, could you go into that in a little more detail?

A. Well, it was a case where we were all sort of communicating with each other as far as exchange of information. And if there was—each one of our files were open for inspection by—well, not inspection but were available to other reviewers, that we had no secrets from each other. Is that what you're referring to?

Q. And if you found information in their card [579] file, what did you do with it then?

A. I would copy it—either copy the card or copy the information. It depended.

Q. And would you then put that information into your card file?

A. Yes, I would.

Q. And if you could not find any information on that particular active ingredient or that particular percentage of the active ingredient in any of the card files of any of the data reviewers, then what would you do?

A. Consult the safety evaluation files. And if nothing was there I would request the data.

Q. What sort of information would you find in the safety evaluation files?

A. The acute studies, acute studies. We had occasionally sub-acutes but by and large there was a limit.

Q. What was the source of this information?

A. This information was gathered on each one of the chemicals that had been submitted by the chemical companies.

Q. Was it primarily public information?

A. No.

Q. It was also information submitted by the company?

A. Yes, it was.

[580] Q. And if you couldn't find any information in that source in the safety evaluation files, then what did you do?

A. I would request the information from the applicant.

Q. But you would only request the information after you had gone through all those steps; is that correct?

A. Yes, I would, that's correct.

Q. Could you tell the Court how many applications you would process following these steps in one day, a typical day?

A. Each one of the reviewers varied in their capacity to produce. And the minimum that—expected performance that was considered of each reviewer was twelve a day. I managed to maintain a level of production of about twenty a day. That was not my initial production figure; of course I had to work up to that because it took me a while to develop my capacity to recognize the chemicals and build up my card file where I could be more productive.

Q. Okay. And during the period from 1966 to 1972 does the procedure you have just described to the Court describe the procedure you followed in your day-to-day review of applications?

A. Yes. Yes, that's the procedure we followed.

Q. Were there any changes in this period?

[581] A. Well, in this period we went through the transition of USDA to EPA.

Q. And upon that transition did you change your procedures for processing applications in any way?

A. No, I did not.

Q. Are you familiar with the compendium of toxicological data which was produced by EPA?

A. There is a compendium of labeling information and toxicology information.

Q. Okay. I'd like to show you exhibits—defendant's Exhibit X. Could you identify what Exhibit X is?

A. Exhibit X is a copy of the looseleaf entries that I prepared for the compendium from my card file.

Q. Okay. And you compared this compendium—you compared this information; is that correct?

A. I prepared it, yes.

Q. And for what purpose did you prepare it?

A. This was prepared so that the reviewer could have a ready reference at his desk of all the information on the chemical to assist him in his review of applications for registration. And I drew on all sources that I could to bring forth in one document everything that would assist the reviewer.

Q. And so this document was prepared to assist all of the toxicology reviewers?

[582] A. Yes, it was.

Q. At EPA at that time?

A. Uh-huh.

Q. How did you prepare this document?

A. It came about because of my voluminous card file that I accumulated over the years. I apparently was the prime candidate to do an undertaking like this. And then as I started it I realized that there were certain shortcomings in my own file as far as the current information that would be available in the fungicide and herbicide group, and the disinfectants. And I issued a memo or I made a request of the other reviewers so that I could have the benefit of their information to be incorporated into this compendium.

Q. And did they supply you with information to be incorporated into the compendium?

A. Yes, they did.

Q. And could you tell the Court how the entires for this document, Exhibit X, were selected from the compendium?

A. They are those chemicals that are registered by Monsanto.

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[584] Q. Was there my any limitation placed on the sources of your information, toxicology information compiled in this compendium?

A. No limitations.

Q. And you drew it from all sources?

A. From all sources available to me to the point of citing PR notices for reference to the reviewer, references

to information that is available in the literature, any and everything, even citing interpretation 18 so that the reviewer would know that this particular chemical does appear in interpretation 18.

Q. And in addition to public literature, would information which was obtained from registrant's files be in this document?

A, I'm sorry?

Q. In addition to the information which had appeared in the public literature, would information which had been obtained from a registrant's files, but had not appeared in the public literature, also be part of this document?

A. Yes, it is.

* * * * *

[586] CROSS-EXAMINATION

By Mr. HEINEMAN:

Q. Mr. Landolt, as I see Exhibit No.—or defendant's Exhibit X here, that appears to be summaries of data, is it not? It's not raw data submitted by the applicant, is it?

A. Inasmuch as defining the quality of the data, no, it doesn't give that kind of information.

Q. Well, for example the toxicological study that is submitted in support of a registration, those studies can take up to fifty-three months to do. Now surely they don't submit in support of a registration something that's like that, do they, half a page long?

A. No.

Q. So what you've done is you've looked at somebody's data and then you've written down a summary that contains label cautions and then acute toxicity information?

A. That's correct.

* * * * *

[590] Q. All right. Now do you know the difference between a commodity and a proprietary chemical?

A. Prior to coming into this courtroom this afternoon I have never heard of those two terms referred to [591] in regard to pesticides.

• • • • •

[593] Q. In connection with your Exhibit W you've got these places you referred to where certain data was blacked out and you didn't know where you got it from. Is that the reason it was blacked out, you couldn't tell for sure whether it was Monsanto's or somebody else's?

A. No, that was Lever Brothers and Monsanto. That was the card that had Lever Brothers and Monsanto on it.

Q. Right. Did you know that Lever Brothers was a customer of Monsanto's for chlorinated triazines?

A. No, I did not.

Q. Do you know whether or not Lever Brothers had Monsanto's permission to obtain a label for a chlorinated triazine?

A. No, I did not.

Q. Do you know whether or not the chlorinated triazines were used as herbicides?

A. No, I can say I really don't recall what uses the triazines had.

[594] Q. Let me direct your attention particularly to page 26 of Exhibit W. Do you know where you got that information?

A. From the Chemical and Engineering News, November 29th, 1971.

Q. Was that chemical listed there ever registered with the EPA?

A. I have no idea.

Q. Let me direct your attention to page 28, and what we have there is apparently a sodium salt of 2-mercaptobenzothiazole; is that correct?

A. Apparently, yes.

Q. Is that a pesticide?

A. I suspect it's a fungicide.

Q. Do you know if Monsanto Company ever used it or registered it as a pesticide?

A. No, I do not. However, I do see from Monsanto's technical bulletin there is a citing of data and some comments on it in the middle of that page.

Q. Right. You got that from a technical bulletin?

A. That's my source.

Q. What is a technical bulletin?

A. Oh, a piece of literature generated by the company for distribution to their clients.

[595] Q. It's a way by which they tell their customers some information about their products?

A. Uh-huh.

Q. Let me direct your attention to page 56. What is represented on that page?

A. Well, we have rodenticide by the common name of Warfarin and registration number by Monsanto of 52469.

* * * * *

By Mr. HEINEMAN:

Q. What is that?

A. Anticoagulant.

Q. Is it a mouse killer?

A. I have it identified on the page as a rodenticide.

Q. Do you know where Warfarin came from?

[596] A. I suspect—I think it was a product produced by WARF Institute

Q. Which is the University of Wisconsin Alumni Research Foundation?

A. Thank you. Yes, sir.

* * * * *

[601] JAMES CODY NELSON [602] was called as a witness, and being first duly sworn to tell the truth, the whole truth and nothing but the truth, testified as follows:

DIRECT EXAMINATION

By Ms. MAYER:

* * * * *

[603] Q. Okay. Could you briefly describe your duties as an attorney with the Grants, Contracts and Administration division at EPA's Office of General Counsel?

A. Yes. My primary responsibility was to work with the Freedom of Information Act, the Privacy Act, and issues related to the confidentiality of business information. We also had other duties that related to Grants and Contracts, other general personnel matters. The Division was sort of a general practice office of the Agency. My primary work, though, was with the Freedom of Information Act, confidentiality of business information. It included giving advice to the various offices in the Agency on those matters, as well as the formal duty of drafting the legal opinions on appeals of Freedom of Information Act requests that were made in the [604] Agency.

* * * * *

[612] A. * * * If the request were for data that had been submitted by an applicant or a registrant under FIFRA, there is a provision of the statute, section 10(g), which provides that the requester must submit an affirmation which, in essence, states that the person making the request is not a foreign or multi-national pesticide producer, and that the person is not an agent for such a producer, and that the person will not negligently or willfully make the information available to such a person. I think we can read that specific language later, if you would like. The affirmation requirement applies to any requester requesting data submitted by an applicant or registrant. If there is an affirmation included within the original request letter, then the office would proceed to the next step, processing the request. If there is no affirmation, they would write back to the requester, saying we cannot further process your request until you submit such an affirmation. And they would send a copy of the form affirmation that we use back to requester, assuming that the requester has signed and submitted an affirmation either with [613] the original request or in response to our communication. The people in that branch would

evaluate the affirmation of the requester to ascertain whether the person, in spite of having signed the affirmation, might be a multi-national or foreign producer, or an agent for such a person. If they were to determine that the person did not qualify under Section 10(g), they would write back to the requester denying the request on the basis that we are not allowed to disclose the information under Section 10(g).

The COURT: Excuse me. Have you ever had any litigation as a result of refusal?

A. We have not, your Honor. We have denied a number of requests on the basis that the requester was not qualified under 10(g) to receive the information. And none of them have ever filed suit against us.

* * * * *

[638] Q. From your experience, could you describe the types of persons who have requested information through the Freedom of Information Act, for data submitted under FIFRA?

A. We have received requests from an infinite variety of people. We have received some requests from companies either in the pesticide business or some other business. We receive many requests from law firms, many of them representing companies in the pesticide business. We receive requests from a very interesting firm that has an office in Rockville, Maryland called FOI Services. And their entire business is making FOI requests on behalf of anonymous parties who don't want the Agency to know who's making the request.

The COURT. Can you put them in jail for perjury for signing——

A. Well, that's the thing. What we found when [639] we asked FOI Services to sign the affirmation, they typically withdraw their request because the whole reason the client goes to them is to maintain their anonymity. And the affirmation from itself requests the identity of the client. And since the client doesn't want to be known, our experience has been that very few of the requests that

come from FOI Services ever get beyond that stage. Many of the requests have come in from legal representatives or offices of the unions representing either farm workers or chemical workers. We have received some requests from individual citizens. We have received requests from environmental and conservation groups such as the National Audubon Society.

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By Ms. MAYER:

Q. Could you continue your answer? Were there any other groups that you were——

A. We received an occasional one. We had some requests from companies who were involved. You heard testimony yesterday on the whole thing of data compensation. We [640] occasionally get requests from companies that's being asked to pay compensation to get a look at the data that they're being asked to pay compensation on. That's one particular example. I have also had an occasion that I have worked on where some local pesticide distributors were trying to pursue an anti-trust action against the pesticide company because they cut off his supply, or something. And they told him the reason was because of something EPA had done in regulating pesticides. So he had written in and asked for the data so he could understand.

The COURT: As I understand it, you're not going to concern yourself with patent, anti-trust or anything of that nature; is that a fair statement?

A. Yes. We do not look into the purpose of the request except to the extent that 10(g) is relevant, of course.

By Ms. MAYER:

Q. Okay. Mr. Nelson, you have stated that you sometimes get requests from pesticide companies or law firms representing pesticide companies. What type of information do they generally request?

A. Well, in the past, certainly before the 1978 amendments of FIFRA, we got a lot of requests from companies basically interested in looking at another company's data.

And by data there, I mean the health and safety data we were referring to. Almost all of them knew along the way that they were not going to get product formulas and things like [641] that. We got many requests for the data, animal studies, residue studies, and so on. After the '78 amendments, once we started sending out letters telling people they had to submit the 10(g) affirmation, what we have seen happen is that the number of requests from companies after—asking for the actual data has dropped considerably. Most of the requests we're now receiving from the companies are for fairly routine items, such as copies of labels that the agency has approved, copies of documents that are used in the RPAR process, and so on. And apparently the companies have all recognized that almost none of them can qualify any more under 10(g), because almost all of them have some foreign business connection and, thus, are not eligible under 10(g). And they have stopped making any requests for the health and safety data because they know they couldn't get it. And instead they're requesting things that are basically public, like the labels.

Q. Eliminating these routine requests for labels, how many of the requests that you get for actual data come from companies in business or law firms representing those companies and, on the one hand, versus groups like union groups or citizens groups, on the other hand?

A. I would say that no more twenty percent of the requests for the health and safety data itself now comes from companies or their representatives.

[642] Q. Do you get requests from scientists and doctors?

A. Yes. We have had requests from scientists. I'm trying to—I can't remember the name, it's a big research institute in New York. I forget the name of it right now. But some people from there requested some data. We have received a few requests from physicians who were concerned about patients who may have been exposed to pesticides, and they wanted to look at the data to see what the effects might be and whether the things their

patients were experiencing were the result of pesticide exposure.

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[648] CROSS-EXAMINATION

By Mr. DYER:

* * * * *

[651] Q. I see. All right. While I'm on this point, and we'll get to it in a bit more detail later. You also have testified to some length about the so-called 10(g) affirmation which was marked as an exhibit here in the proceedings this morning. Is that a regulation?

A. The 10(g) affirmation?

Q. Yes.

A. No, the affirmation is not a regulation.

Q. I see. Are there specific regulations that have been promulgated pursuant to 10(g)?

A. There are no regulations since the amendment of our FOI regulations in, I believe, September of '78.

Q. Well——

A. That's prior to the FIFRA amendments. So there have been no FOI regulations specifically to the '78 amendments to FIFRA.

Q. Mr. Nelson, my question though is have there been regulations promulgated pursuant to section 10(g) of FIFRA of 1978?

A. There have not been regulations promulgated about section 10(g). I don't know that regulations have been promulgated pursuant to section 10, but there are no regulations about 10(g).

[652] Q. Now, we're all aware that the subject of section 10(g) deals with foreign or multi-national pesticide producers?

A. Right.

A. Has the Agency promulgated a written definition of what that term is?

A. There is no definition other than what appears in the interim procedures which is the statutory language.

* * * * *

[653] Q. Are you familiar with a company that's located in Kansas City, Kansas called Thompson Hayward Chemical Company?

A. Yes, I have some—I mean I know who they are. I know they're in the pesticide business.

Q. Would they, under your interpretation of foreign or multi-national, be a foreign or multi-national pesticide producer?

A. I don't recall whether we have ever had to rule on that. I would have to know more facts about them, where their business is, what they do, and so on. The fact that they're in the U.S. alone doesn't mean they're not; but I would have to know what foreign business they have.

Q. All right. Then since you don't know about Thompson Hayward specifically, let's take it from the other side. You say it's apparent what a foreign or multi-national pesticide producer is; what is a non-foreign or multi-national pesticide producer in the EPA's interpretation? Can you tell [654] me that?

A. Well, firstly, every company that has nothing to do with pesticides, anyone who's not——

Q. Let's limit it to pesticide companies.

A. Okay. The company whose business is solely in the U.S., does no exporting would not be.

Q. Any others, any other requirements?

A. Not that I can think of.

Q. Let's assume that one of those companies that fits your interpretation at some point in time makes a request for data, and because they are not a foreign or multi-national pesticide producer, they quite properly sign the affirmation. And data is then—ultimately, after your procedures have all been followed correctly and exhausted, pesticide data is disclosed to them by the Environmental Protection Agency. Now let's further assume that at some point in time, maybe years down the road or

maybe not so long, that company is acquired by another company that is in fact a foreign or multi-national pesticide producer. What happens in that situation?

A. EPA's action is complete so nothing would happen from our point of view.

* * * * *

[658] By Mr. DYER:

Q. I want to draw your attention to the language in 10(G) which I believe is in fact that last sentence. And it says in part, notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, and so on?

A. Uh-huh.

[659] Q. Now what's a public proceeding?

A. Well, I'll have to refer you to our interim policy where we talk about how we will implement that.

Q. Well, let me ask you this. I'm sure you're familiar with a procedure that EPA has developed over the years called rebuttable presumption against registration, and goes by the term RPAR?

A. Uh-huh.

[659] Q. Is that a public proceeding?

A. I do not specifically work on the RPAR proceedings so I don't know if that would be characterized as one under this.

Q. Well, all right. There are provisions in other sections of the statute dealing with procedures by which the registration of a pesticide may be cancelled. And they have come to be known as cancellation proceedings, and they are in fact administrative proceedings which have been held. And I think in fact one is going on now, at least one where hearings are held, and so forth. Now, are those cancellation proceeding public proceedings?

A. Again, I don't have special expertise in those proceedings. There are aspects of them that are public, but I'm aware of a particular proceeding involving Dow

Chemical and 2, 4, 5-T where in fact some of the matters in it have been sealed or held in confidential sections.

Q. But isn't it true, Mr. Nelson, that the reason that those documents in the *Dow* case were presented—were disclosed by Dow under a protective order was because at the time, the Dow Chemical Company had an injunction in the Eastern District Court in Michigan which enjoined the EPA from disclosing their data, and wasn't that the purpose of the protective order in that case?

A. That is my understanding.

[661] * * * * * *

Q. All right. Now, I may be confused and I want both myself and the record to be clear. You were talking about the types of requests that you got from pesticide companies. And I believe you said that prior to the '78 amendments you got a large volume of requests for data from pesticide companies. Well, Mr. Nelson, under the 1972 amendments to FIFRA and also the 1975 amendments, didn't section 10 at that time protect trade secret data?

A. Well, that would call for a judgment on—certainly data was always protected under section 10(b), some data. Now what data that was in fact, the agency has extensive [662] litigation with companies over whether or not health and safety fit within that.

Q. And didn't that litigation ultimately result in the conclusion by at least three or four courts that what you characterize as health and safety data was in fact trade secret within the definition of the restatement of torts, and was in fact protected; and further, wasn't the Agency enjoined from disclosing data of at least two or three of those chemical companies?

A. There were decisions to that effect, but that doesn't prevent people from making requests.

Q. Well, if there were these large volumes of requests made prior to '78, were you disclosing this trade secret data prior to 1978?

A. Very little, if any, data was being disclosed.

Q. Now, I want to ask you again as briefly as I can about one other area. You have been here in the courtroom for the last two or three days, and no doubt have heard reference made to, and certainly have seen sitting over there on that cart, a rather large volume of pesticide data which has been described as the data submitted by Monsanto Company in support of registration on its product called Roundup. In connection with that I want to hand you a copy of what was previously marked Plaintiff's Exhibit 39, and I'd ask you to take a look at that.

[663] * * * * *

Q. Now, in reviewing Exhibit 39, would it be your opinion that the information contained therein would not be disclosable under the 1978 amendments to FIFRA under section 10 or 3?

A. Let me say two things about it. There are some things on it that clearly are not confidential, like the identity of the pesticide—the chemical identity of the active ingredient. I don't think anyone is alleging those are confidential. The chemical properties of the active ingredient presumably are not confidential also. There is the composition of the formulated product, and that is one of the things that can be confidential under the '78 amendments. It's not automatically confidential but assuming the company can show that [664] it is, it can be treated as confidential under the statute, and is not required to be disclosed. Same thing with respect to manufacturing process which appears on the second page. And I'm not exactly sure what the rest of the document is about. At the bottom of that page, it's talking about some kind of test and I'm not sure what it's testing, because I'm not a chemist. It says determination of N-phospho, blah, blah, blah, blah, blah, and I'm not sure if this is some physical chemical property test or whether this is a health and safety test, so I couldn't tell you what the status of that last part would be. But it does describe some method for testing something. It might be a method for identifying an inert, in which case it would be eligible

for confidential treatment. And it might be a thing that is merely telling you something about the properties of the pesticide vis-a-vis mammals or fish or something, in which case it wouldn't be. But I couldn't tell you without knowing more about it. Again, it's a case where you would have to tell me as the company if it's confidential and why; and then I would have to evaluate that.

Q. That was going to be my next question. If you were still employed in your job that you had prior to December, 1979 where you were dealing with these matters, would you be [665] called upon—and assuming that it were requested and Monsanto asserted confidential treatment, would you be called upon to make a determination as to whether that document was in fact protected?

A. Certainly.

Q. All right. Now, I want to direct your attention over there to all those other documents. And I realize at the outset that you—at least I presume that you have never had an opportunity nor a desire nor a reason to review all those documents?

A. No, I haven't.

Q. And I'm certainly not going to ask you to do that at this time. But I want to represent to you that there has been testimony that the information contained in those documents is in fact the information, research and test data which the Monsanto Company has submitted to the Environmental Protection Agency in support of its registration on the pesticide Roundup. And I also want to represent to you that several categories of information, research and test data are contained in those documents. And I want to go through those categories of documents, and I want you to assume that that particular type of information is in fact represented there. And I want to then ask you whether, assuming requests were made and your procedures were followed, whether that particular type of information would be disclosable under section 3 or 10 of the 1978 amendments to FIFRA?

A. Let me just, as a preliminary question, again [666] just to set the stage, this is a registered or previously registered pesticide?

Q. Roundup? It is a registered pesticide.

A. So 10 would apply?

Q. It would. We will further assume that. That is a fact. What about the category of information, research and test data characterized as efficacy studies; would those be disclosable under section 10?

A. With the caveat that material described in 10(d)(1)(A), (B), (C) is not required to be disclosed, my understanding of what you're referring to as efficacy data would fall within the description of 10(d)(1).

Q. What about the category known as phytotoxicity data?

A. I heard that term yesterday and I'm not sure what it means. If you wouldn't mind explaining the term to me?

Q. Well, I wouldn't do that. If you don't know then you can't at this time make that determination. What about metabolism and residue studies?

A. My understanding is that metabolism and residue studies again would fall within 10(d)(1).

Q. What about environmental chemistry data?

A. My understanding is that has to do with fate and the environment, and that would fall within 10(d)(1).

[667] Q. What about toxicology studies?

A. That would fall within 10(d)(1).

Q. What about fish and wildlife studies?

A. That would fall within 10(d)(1).

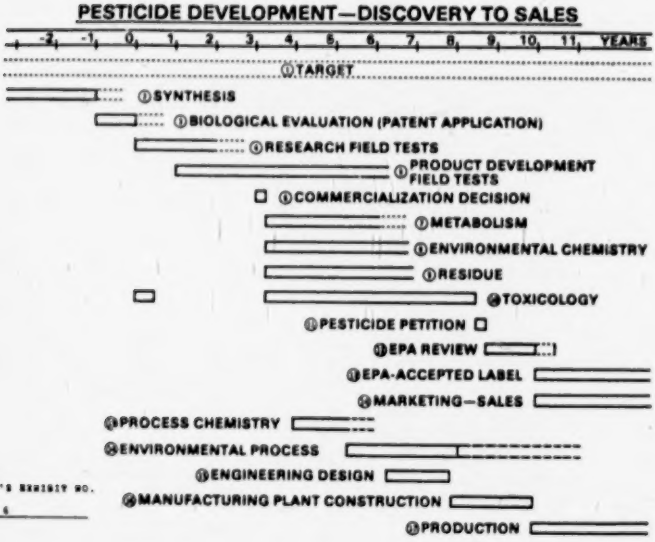
Q. And so then is it fair to say, Mr. Nelson, if you will assume that the categories I have just described are what is comprised in that mass of information, research and test data except that which is set out in Exhibit 39, then is it not a fact that under section 10 of the 1978 amendments to FIFRA, all of that data would be disclosable?

A. To people who qualify under 10(g).

Mr. DYER. Right. That's all the questions I have.

* * * * *

Plaintiff's Exhibit 6



Supreme Court of the United States

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

MONSANTO COMPANY

Appeal from the United States District Court for the Eastern District of Missouri.

The statement of jurisdiction in this case having been submitted and considered by the Court, in this case probable jurisdiction is noted.

OCTOBER 11, 1983.

Justice White took no part in the consideration or decision of this case.

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